INTERNATIONAL STANDARD

ISO 80601-2-13

First edition
2011-08-01

Medical electrical equipment —

Part 2-13:
Particular requirements for basic safety and essential performance of an anaesthetic workstation

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 80601-2-13 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice,* Subcommittee SC D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-13 cancels and replaces the following:

— ISO 8835-2:2007, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems*

— ISO 8835-3:2007, *Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

— ISO 8835-4:2004, *Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices*

— ISO 8835-5:2004, *Inhalational anaesthesia systems — Part 5: Anaesthetic ventilators*

— IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

This edition constitutes a major technical revision of the material that was contained in the previous standards by consolidating it into a single document, removing duplications and inconsistencies as well as harmonization with the third edition of IEC 60601-1.

Introduction

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— Test specifications: italic type.

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— Terms defined in Clause 3 of the general standard, in this particular standard or as noted: small capitals.

In referring to the structure of this standard, the term

— "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this International Standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

This International Standard considers both an ANAESTHETIC WORKSTATION supplied complete and its individual components. It has been structured to allow RESPONSIBLE ORGANIZATIONS to configure an ANAESTHETIC WORKSTATION from individual components in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, this International Standard identifies particular

requirements pertinent to specific ANAESTHETIC WORKSTATION components, and to their associated MONITORING EQUIPMENT, ALARM SYSTEM(S) and PROTECTION DEVICE(S), and defines the interfaces.

Figure 201.101 is a graphical representation of the structure of this International Standard and is provided for informational purposes only.

ANAESTHETIC WORKSTATION		
General requirements Clauses 201.1 – 201.17, 201.106, 201.107, 202-211	MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES	Mandatory elements; see also Table AA.1
ANAESTHETIC GAS DELIVERY SYSTEM Clause 201.101		
ANAESTHETIC BREATHING SYSTEM Clause 201.102		
ANAESTHETIC GAS SCAVENGING SYSTEM Clause 201.103	MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES	Optionally present; see also Table AA.1
ANAESTHETIC VAPOUR DELIVERY SYSTEM Clause 201.104		
ANAESTHETIC VENTILATOR Clause 201.105		

Figure 201.101 — Configuration of an ANAESTHETIC WORKSTATION and corresponding organization of this International Standard

Medical electrical equipment —

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

201.1 Scope, object and related standards

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of an ANAESTHETIC WORKSTATION for administering inhalational anaesthesia whilst continuously attended by a professional OPERATOR.

This International Standard specifies particular requirements for a complete ANAESTHETIC WORKSTATION and the following ANAESTHETIC WORKSTATION components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant ANAESTHETIC WORKSTATION components, to form an ANAESTHETIC WORKSTATION to a given specification:

— ANAESTHETIC GAS DELIVERY SYSTEM;

— ANAESTHETIC BREATHING SYSTEM;

— ANAESTHETIC GAS SCAVENGING SYSTEM;

— ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— ANAESTHETIC VENTILATOR;

— MONITORING EQUIPMENT;

— ALARM SYSTEM;

— PROTECTION DEVICE.

NOTE 1 MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES are summarized in Table AA.1.

An ANAESTHETIC WORKSTATION supplied complete and its individual components are considered as ME EQUIPMENT or ME SYSTEMS with regard to the general standard.

NOTE 2 The applicability of this International Standard is indicated in Table AA.2.

This International Standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to an ANAESTHETIC WORKSTATION where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ANAESTHETIC WORKSTATION.

If a clause or subclause is specifically intended to be applicable to ANAESTHETIC WORKSTATION components only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to an ANAESTHETIC WORKSTATION and its individual components, as relevant.

HAZARDS inherent in the intended physiological function of an ANAESTHETIC WORKSTATION and its individual components within the scope of this International Standard are not covered by specific requirements in this International Standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 3 See also 4.2 of the general standard.

This International Standard is not applicable to any ANAESTHETIC WORKSTATION intended for use with flammable anaesthetic agents, as determined by Annex BB.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an ANAESTHETIC WORKSTATION and its individual components designed for use in the ANAESTHETIC WORKSTATION (as defined in 201.3.211) and its ACCESSORIES.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3:2008 and IEC 60601-1-11:2010 do not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 206.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-6 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 to 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for IEC 60601-1-6, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

Replace references to ISO 2878, ISO 15223, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 by the following:

ISO 2878:2005, *Rubber — Antistatic and conductive products — Determination of electrical resistance*

ISO 15223-1:—[1], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

ISO 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections* [alternative normative reference to ISO 5145]

ISO 594-2:1998[2] , *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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1) To be published.

2) To be revised by ISO 80369-7, *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*, which is under preparation.

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning* [alternative normative reference to ISO 407]

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2:2006, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

ISO 5360:2006, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5362:2006, *Anaesthetic reservoir bags*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 8836, *Suction catheters for use in the respiratory tract*

ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9170-2, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements* [alternative normative reference to ISO 10079-3]

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source* [alternative normative reference to ISO 10079-1]

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 80601-2-55:—[3]), *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60079-11, *Explosive atmospheres — Part 11: Equipment protection by intrinsic safety "i"*

IEC 60079-20-1, *Explosive atmospheres — Part 20-1: Material characteristics for gas and vapour classification — Test methods and data*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

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3) To be published.

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

IEC 62304:2006, *Medical device software — Software life cycle processes*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006 and the following apply.

NOTE An index of defined terms is found at the end of this document.

Addition:

201.3.201
ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM
ANAESTHETIC GAS SCAVENGING SYSTEM in which gas flow in the DISPOSAL SYSTEM results from a POWER DEVICE

NOTE Adapted from ISO 4135:2001, definition 7.1.2.

201.3.202
AIRWAY PRESSURE
pressure at the PATIENT CONNECTION PORT

201.3.203
ANAESTHETIC BREATHING SYSTEM
inspiratory and expiratory pathways through which ANAESTHETIC GAS flows at respiratory pressure between the FRESH-GAS INLET, the PATIENT CONNECTION PORT and an EXHAUST VALVE or EXHAUST PORT

NOTE Adapted from ISO 4135:2001, definitions 3.1.6 and 4.1.1.

201.3.204
ANAESTHETIC GAS
gases and, if present, vapour of a volatile anaesthetic agent, used in anaesthesia

NOTE In parts of an ANAESTHETIC BREATHING SYSTEM, ANAESTHETIC GAS includes gases exhaled by the PATIENT.

201.3.205
ANAESTHETIC GAS DELIVERY SYSTEM
ANAESTHETIC WORKSTATION component that receives separate supplies of MEDICAL GAS(ES) and delivers mixed gases in concentrations or individual flow rates adjustable by the OPERATOR

NOTE An ANAESTHETIC GAS DELIVERY SYSTEM can include a means of flow rate adjustment control, FLOWMETERS or a gas mixer and ANAESTHETIC GAS DELIVERY SYSTEM PIPING but does not include vaporizers.

201.3.206
ANAESTHETIC GAS DELIVERY SYSTEM PIPING
all piping, including unions, from the UNIDIRECTIONAL VALVES in the pipeline inlets and from the outlets of the PRESSURE REGULATOR(S) to the means of flow rate adjustment control, as well as the piping connecting the

means of flow rate adjustment control and the piping connecting the ANAESTHETIC VAPOUR DELIVERY SYSTEM to the FRESH-GAS OUTLET

NOTE ANAESTHETIC GAS DELIVERY SYSTEM PIPING includes piping leading to and from pneumatic loss of pressure ALARM SIGNAL generators, pressure indicators, the oxygen flush and gas power outlets.

201.3.207
ANAESTHETIC GAS SCAVENGING SYSTEM
PROTECTION DEVICE that is connected to an ANAESTHETIC BREATHING SYSTEM or to associated equipment for the purpose of conveying excess ANAESTHETIC GAS to an appropriate place of discharge

NOTE 1 Adapted from ISO 4135:2001, definition 7.1.1.

NOTE 2 Functionally, an ANAESTHETIC GAS SCAVENGING SYSTEM comprises three different parts: a TRANSFER SYSTEM, a RECEIVING SYSTEM and a DISPOSAL SYSTEM. These three functionally discrete parts can be either separate or sequentially combined in part or in total. In addition, one or more parts of an ANAESTHETIC GAS SCAVENGING SYSTEM can be sequentially combined with an ANAESTHETIC BREATHING SYSTEM or an ANAESTHETIC VENTILATOR, to include the TRANSFER SYSTEM or the TRANSFER and RECEIVING SYSTEM.

201.3.208
ANAESTHETIC PATIENT VALVE
valve at the PATIENT end of an ANAESTHETIC BREATHING SYSTEM that has three operating functions:

— as a UNIDIRECTIONAL VALVE to prevent flow towards the vaporizer during exhalation,

— as an inflating valve to permit intermittent positive-pressure ventilation, and

— as a unidirectional EXHAUST VALVE to prevent inhalation of air through the EXHAUST PORT during spontaneous ventilation

201.3.209
ANAESTHETIC VAPOUR DELIVERY SYSTEM
ANAESTHETIC WORKSTATION component that provides the vapour of a volatile anaesthetic agent in a calibrated concentration

NOTE Adapted from ISO 4135:2001, definition 2.2.2.

201.3.210
ANAESTHETIC VENTILATOR
ANAESTHETIC WORKSTATION component that is connected via the ANAESTHETIC BREATHING SYSTEM to the PATIENT'S airway and automatically augments or provides ventilation during anaesthesia

201.3.211
ANAESTHETIC WORKSTATION
system for administering inhalational anaesthesia that contains an ANAESTHETIC GAS DELIVERY SYSTEM, an ANAESTHETIC BREATHING SYSTEM and any required MONITORING EQUIPMENT, ALARM SYSTEMS, and PROTECTION DEVICES

NOTE The ANAESTHETIC WORKSTATION can also include, but is not limited to, one or more of the following: ANAESTHETIC VAPOUR DELIVERY SYSTEM, ANAESTHETIC VENTILATOR, ANAESTHETIC GAS SCAVENGING SYSTEM, and any associated MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES.

201.3.212
BREATHING TUBE
non-rigid tube used to convey ANAESTHETIC GAS between components of an ANAESTHETIC BREATHING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.1.2.

201.3.213
CIRCLE ABSORBER ASSEMBLY
part of a CIRCLE BREATHING SYSTEM that comprises one or more carbon-dioxide-absorbent containers, INSPIRATORY and EXPIRATORY VALVES or other means of ensuring unidirectional gas flow, two ports for connection to BREATHING TUBES, a FRESH-GAS INLET, and a reservoir bag port or an ANAESTHETIC VENTILATOR port or both

201.3.214
CIRCLE BREATHING SYSTEM
ANAESTHETIC BREATHING SYSTEM in which the direction of gas flow through inspiratory and expiratory pathways is unidirectional and in which the two pathways form a circle

201.3.215
DANGER ZONE
any zone within and/or around an ANAESTHETIC WORKSTATION in which a person is subject to a RISK to their health or safety from the powered movement of the ANAESTHETIC WORKSTATION or its components

201.3.216
DELIVERED VOLUME
V_{DEL}
volume of gas delivered through a PATIENT CONNECTION PORT during a breath

NOTE 1 Adapted from ISO 4135:2001, definition 3.4.2.

NOTE 2 DELIVERED VOLUME is also referred to as tidal volume when all of the DELIVERED VOLUME enters the PATIENT'S respiratory tract. This is frequently not the case when there is significant TRACHEAL TUBE cuff leakage (as in neonates) or in non-invasive ventilation.

201.3.217
DISPOSAL HOSE
part of an ANAESTHETIC GAS SCAVENGING SYSTEM that conveys excess ANAESTHETIC GAS from the RECEIVING SYSTEM to the DISPOSAL SYSTEM

201.3.218
DISPOSAL SYSTEM
part of an ANAESTHETIC GAS SCAVENGING SYSTEM by means of which the excess ANAESTHETIC GAS is conveyed to the point of discharge

NOTE The point of discharge can be, for example, the exterior of a building or a non-recirculating extract ventilation system.

201.3.219
EXHAUST PORT
port through which waste or excess ANAESTHETIC GAS is discharged to the atmosphere or to an ANAESTHETIC GAS SCAVENGING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.2.1.6.

201.3.220
EXHAUST VALVE
valve connected to an EXHAUST PORT

NOTE An ADJUSTABLE PRESSURE-LIMITING (APL) VALVE can be an EXHAUST VALVE.

201.3.221
EXHAUST FLOW RATE
flow rate of gas from the RECEIVING SYSTEM at the entry to the DISPOSAL SYSTEM

201.3.222
FRESH GAS
respirable gas delivered to an ANAESTHETIC BREATHING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 3.1.8.

201.3.223
FRESH-GAS INLET
port through which FRESH GAS enters the ANAESTHETIC BREATHING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.2.1.5.

201.3.224
FRESH-GAS OUTLET
port through which FRESH GAS is delivered from the ANAESTHETIC GAS DELIVERY SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.2.1.1.

201.3.225
HIGH-FLOW TRANSFER AND RECEIVING SYSTEM
TRANSFER and RECEIVING SYSTEM that connects to a high-flow-rate DISPOSAL SYSTEM

201.3.226
INDUCED FLOW RATE
flow rate at the inlet of the TRANSFER SYSTEM, that is generated by the DISPOSAL SYSTEM

201.3.227
LOW-FLOW TRANSFER AND RECEIVING SYSTEM
TRANSFER and RECEIVING SYSTEM that connects to a low-flow-rate DISPOSAL SYSTEM

201.3.228
MAXIMUM EXHAUST FLOW RATE
largest EXHAUST FLOW RATE that can be accommodated without exceeding the specified limitations for INDUCED FLOW RATE

201.3.229
MAXIMUM LIMITED PRESSURE
highest pressure at the PATIENT CONNECTION PORT during NORMAL USE and under a SINGLE FAULT CONDITION

NOTE Adapted from ISO 4135:2001, definitions 3.3.3 and 3.3.4.

201.3.230
MINIMUM EXHAUST FLOW RATE
smallest EXHAUST FLOW RATE that ensures that the specified limit of SPILLAGE to atmosphere is not exceeded

201.3.231
MONITORING EQUIPMENT
ANAESTHETIC WORKSTATION component that continuously or continually measures and displays the value of a variable to the OPERATOR

201.3.232
PATIENT CONNECTION PORT
port of an ANAESTHETIC BREATHING SYSTEM, intended for connection to the connector of an airway device

NOTE Adapted from ISO 4135:2001, definition 4.2.1.2.

EXAMPLE PATIENT CONNECTION PORT can connect to a TRACHEAL TUBE, TRACHEOSTOMY TUBE, face mask or supraglottic device.

201.3.233

POWER DEVICE

component of the DISPOSAL SYSTEM of an ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM that generates the EXHAUST FLOW RATE

201.3.234

POWER SUPPLY

source of energy other than that generated directly by the human body or by gravity that makes the device function

EXAMPLE SUPPLY MAINS, INTERNAL ELECTRICAL POWER SOURCE, compressed gas from a MEDICAL GAS PIPELINE SYSTEM or cylinder.

201.3.235

PROTECTION DEVICE

device that without intervention by the OPERATOR, protects the PATIENT, OPERATOR or others from hazardous output due to incorrect delivery or removal of energy or substances

201.3.236

RECEIVING SYSTEM

part of an ANAESTHETIC GAS SCAVENGING SYSTEM that provides an interface between the TRANSFER SYSTEM and the DISPOSAL SYSTEM

201.3.237

SPILLAGE

volume of ANAESTHETIC GAS that cannot be accommodated by the ANAESTHETIC GAS SCAVENGING SYSTEM over a specified period

201.3.238

TRANSFER SYSTEM

component of an ANAESTHETIC GAS SCAVENGING SYSTEM, which can incorporate a transfer tube, that transfers ANAESTHETIC GAS from the EXHAUST PORT of an ANAESTHETIC BREATHING SYSTEM, or associated equipment to the RECEIVING SYSTEM

201.3.239

Y-PIECE

3-way connector with a PATIENT CONNECTION PORT and two ports for connection to BREATHING TUBES

201.4 General requirements

IEC 60601-1:2005, Clause 4 applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

Additional ESSENTIAL PERFORMANCE requirements are identified in the subclauses listed in Table 201.101.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Oxygen flow under all conditions except the failure of the oxygen supply (pipeline or cylinder) to the ANAESTHETIC WORKSTATION or the generation of a TECHNICAL ALARM CONDITION	201.12.4.107.2 (oxygen supply failure PROTECTION DEVICE) 201.101.2 (interruption of the electrical POWER SUPPLY) 201.101.8 (oxygen flush)
Delivery of a non-hypoxic gas mixture to the PATIENT or generation of a TECHNICAL ALARM CONDITION	201.11.8.102 (ALARM CONDITION for POWER SUPPLY failure) 201.11.8.103 (INTERNAL ELECTRICAL POWER SOURCE) 201.12.4 (protection against hazardous output) 201.101.4.2.3 (reserve flow and cross flow PROTECTION DEVICE) 201.101.7 (gas mixers) 201.101.8 (oxygen flush)
Non-delivery of excessive concentrations of a volatile anaesthetic agent or generation of a TECHNICAL ALARM CONDITION	201.104.2 (delivered vapour concentration) 201.12.4.103.3 (anaesthetic agent MONITORING EQUIPMENT)
AIRWAY PRESSURE monitoring and associated alarm	201.12.4.109 (AIRWAY PRESSURE MONITORING EQUIPMENT)

201.4.10 POWER SUPPLY

Addition:

201.4.10.101 * Requirements for pneumatic power input

The ANAESTHETIC WORKSTATION or its individual components shall operate and meet the requirements of this International Standard throughout the RATED range of inlet pressures and shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION to a maximum pressure of 1 000kPa (10 bar).

If the ANAESTHETIC WORKSTATION or individual ANAESTHETIC WORKSTATION component is intended to be connected to either

— a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1 via TERMINAL UNITS complying with ISO 9170-1 and flexible hose connections complying with ISO 5359, or

— a PRESSURE REGULATOR complying with ISO 10524-1,

then

— the RATED range of inlet pressures shall cover the range specified in those standards,

— the time-weighted average input flow (over 10 s) required by the ANAESTHETIC WORKSTATION or all individual ANAESTHETIC WORKSTATION components for each gas shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas inlet port, with the oxygen flush not activated,

— the transient input flow shall not exceed the equivalent of 200 l/min for 3 s.

NOTE 1 Internal PRESSURE REGULATORS can be required to accommodate the RATED range of inlet pressure and the SINGLE FAULT CONDITION of maximum inlet pressure.

NOTE 2 Under the SINGLE FAULT CONDITION of overpressure of twice the maximum RATED inlet pressure, it is desirable for gas to continue to flow to the ANAESTHETIC BREATHING SYSTEM. Under this condition, the flow rate from the ANAESTHETIC WORKSTATION is likely to be outside its specification.

NOTE 3 Flow values are expressed under STPD conditions (Standard Temperature and Pressure Dry); see 201.7.4.3.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings (e.g. highest driving gas consumption, highest FRESH GAS delivery and highest RATED gas consumption at any gas POWER SUPPLY output, if provided, but without activating the oxygen flush).

201.5 General requirements for testing ME EQUIPMENT

IEC 60601-1:2005, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional general requirements for testing of ANAESTHETIC WORKSTATIONS and ANAESTHETIC WORKSTATION components

201.5.101.1 Test conditions

The ambient temperature for the duration of each test should be between 20 °C and 25 °C, except where otherwise stated.

The accuracy of the test equipment used to carry out gas measurements shall be ±5 % of the variable to be measured, except where otherwise stated. Dry air should be used as the test gas, except where otherwise stated.

201.5.101.2 * Gas flow rate and leakage specifications

Gas flow rate, volume and leakage specifications in this International Standard are expressed at STPD (Standard Temperature and Pressure Dry) except for those associated with the ANAESTHETIC BREATHING SYSTEM, which are expressed at BTPS (Body Temperature and Pressure Saturated).

NOTE 1 For the purposes of this International Standard, STPD is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this International Standard, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

Correct all test measurements to STPD or BTPS, as appropriate.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005, Clause 7 applies, except as follows:

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replacement:

The ANAESTHETIC WORKSTATION and its individual components shall be marked with the safety sign for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005+TC1, Table D.2, number 10).

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Addition:

201.7.2.101 Marking with year of manufacture or use-by date

The ANAESTHETIC WORKSTATION and its OPERATOR-detachable components or their packaging shall be marked with the year of manufacture except for single use devices and those covered by a use-by date (see symbol 5.1.4 of ISO 15223-1:—).

NOTE The MANUFACTURER'S attention is drawn to the importance of consistent use of indication for single-use devices.

If applicable, the ANAESTHETIC WORKSTATION and its OPERATOR-detachable components or their packaging shall be marked with a use-by date (see symbol 5.1.4 of ISO 15223-1:—).

Check compliance by inspection.

201.7.2.102 OPERATOR-detachable, flow-direction-sensitive components

Any OPERATOR-detachable components of the ANAESTHETIC WORKSTATION that are flow-direction-sensitive, unless designed in such a way that prevents incorrect assembly, shall be marked with an arrow showing the direction of flow.

Check compliance by inspection.

201.7.2.103 OPERATOR-accessible GAS-SPECIFIC inlet and outlet

Each OPERATOR-accessible GAS-SPECIFIC inlet and outlet shall be marked with the gas name or chemical symbol in accordance with Table 6 of ISO 5359:2008. If colour coding is used it shall be in accordance with Table 6 of ISO 5359:2008.

Check compliance by inspection.

201.7.2.104 * OPERATOR-accessible gas POWER SUPPLY outlet

Each OPERATOR-accessible gas POWER SUPPLY outlet shall be marked with the RATED output pressure and RATED flow rate.

EXAMPLE 1 280 kPa - 600 kPa, 20 l/min.

EXAMPLE 2 280 kPa - 600 kPa, 20 l/min - 40 l/min.

Check compliance by inspection.

201.7.2.105 Devices containing phthalates

If parts of the ANAESTHETIC WORKSTATION or its individual components in contact with gas to be inhaled by the PATIENT contain phthalates, which are known to be carcinogenic, mutagenic or toxic to reproduction, the ANAESTHETIC WORKSTATION and its individual components shall be marked accordingly.

NOTE The symbol given in Reference [18] can be used.

Check compliance by inspection.

201.7.2.106 * Marking with mass

The ANAESTHETIC WORKSTATION and its individual components shall be legibly and durably marked with its/their mass in its/their NOMINAL configuration, in kilograms (kg).

Check compliance by inspection.

201.7.2.107 Cylinder and pipeline pressure indicators

All cylinder and pipeline pressure indicators shall be identified with the gas name or the chemical symbol in accordance with Table 6 of ISO 5359:2008. If colour coding is used it shall be in accordance with Table 6 of ISO 5359:2008.

Check compliance by inspection.

201.7.4.2 * Control devices

Addition:

Each GAS-SPECIFIC flow rate adjustment control of an ANAESTHETIC GAS DELIVERY SYSTEM shall be identified with the gas that it controls by the gas name or the chemical symbol in accordance with Table 6 of ISO 5359:2008. If colour coding is used it shall be in accordance with Table 6 of ISO 5359:2008. Each flow rate adjustment control of an ANAESTHETIC GAS DELIVERY SYSTEM shall be marked with an indication of how to increase and decrease the gas flow rate. If applicable, the point of reference for reading the flow rate indication shall be identified.

NOTE A multifunctional control that can be used to control multiple items is not considered a GAS-SPECIFIC control.

The oxygen flush control shall be marked with one of the following:

— “Oxygen Flush”, or

— “O_2 Flush”, or

— “O_2 +”.

201.7.4.3 * Unit of measure

Addition:

All gas volume, flow and leakage specifications shall be expressed as STPD, except those associated with the ANAESTHETIC BREATHING SYSTEM, which shall be expressed as BTPS.

NOTE 1 For the purposes of this International Standard, STPD is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this International Standard, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

201.7.9.1 General

Replacement:

Replace the first dash with:

— name or trade name and address of

  — the MANUFACTURER, and

  — where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the RESPONSIBLE ORGANIZATION can refer.

201.7.9.2.1 General

Addition:

The instructions for use shall contain the date of issue or the latest revision.

For ANAESTHETIC WORKSTATIONS not supplied complete, the instructions for use shall contain, as far as applicable, information about the MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES required by this International Standard and how to connect them.

201.7.9.2.2 * Warnings and safety notices

Addition:

The instructions for use shall contain a statement to the effect that, in case of ANAESTHETIC WORKSTATION failure, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT injury.

EXAMPLE An alternative means of ventilation would be a self-inflating, manually-powered RESUSCITATOR (see ISO 10651-4) with mask.

201.7.9.2.8 * Start-up PROCEDURE

Amendment:

Delete the given EXAMPLE and add the following text at the end of the subclause:

The instructions for use shall contain at least one OPERATOR pre-use checklist.

EXAMPLE 1 Beginning of day or shift pre-use checklist.

EXAMPLE 2 Between PATIENTS pre-use checklist.

NOTE Attention is drawn to additional pre-use checklists required by regional or national medical associations or authorities with jurisdiction.

Electronic displays integral to, or provided with, the ANAESTHETIC WORKSTATION or its individual components may be used to provide such a pre-use checklist.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use of the ANAESTHETIC WORKSTATION and its individual components shall include the following:

aa) information on the method of enabling the ANAESTHETIC WORKSTATION or its individual components, including the MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES, required by this International Standard; this information may form part of the pre-use checklist (see 201.7.9.2.8);

bb) the conditions under which the measured values are displayed, e.g. BTPS, STPD;

cc) where an ANAESTHETIC WORKSTATION is not supplied complete, a statement to the effect that whoever assembles the ANAESTHETIC WORKSTATION from individual components shall provide the pre-use checklist for the ANAESTHETIC WORKSTATION (see 201.7.9.2.8);

dd) where applicable, a statement to the effect that a malfunction of the MEDICAL GAS PIPELINE SYSTEM can cause one or more ANAESTHETIC WORKSTATIONS and other ANAESTHETIC WORKSTATION components connected to the MEDICAL GAS PIPELINE SYSTEM to stop their operation simultaneously; this is not applicable to ANAESTHETIC WORKSTATIONS that only use cylinders for gas supply;

ee) where applicable, disclosure of the presence of all natural rubber latex-based components and their location (see also Symbol 5.4.5 in ISO 15223-1:—;

ff) where applicable, whether the ANAESTHETIC WORKSTATION or its individual components is/are suitable for use in a magnetic resonance imaging (MRI) environment and any related restrictions;

gg) if an ANAESTHETIC WORKSTATION or its individual components is/are used for the treatment of children or treatment of pregnant or nursing women, the RESIDUAL RISK from phthalates that are carcinogenic, mutagenic or toxic to reproduction;

hh) for single-use ACCESSORIES to the ANAESTHETIC WORKSTATION or its individual components, disclosure of the RISKS associated with reusing; this information may be given upon request.

201.7.9.3 Technical description

Addition:

201.7.9.3.101 Components

The technical description shall describe the maximum weight of components, as well as the height of and length of arms on which these components may be mounted on the ANAESTHETIC WORKSTATION or its individual components so as not to compromise the stability requirements tested in IEC 60601-1:2005, Clause 9.

Check compliance by inspection of the technical description.

201.7.9.3.102 ANAESTHETIC WORKSTATIONS intended to be mounted to a wall or ceiling pendant

For ANAESTHETIC WORKSTATIONS intended to be mounted to a wall or a ceiling pendant and that are not considered mobile equipment and consequently need not comply with the requirement on moving over a threshold in 201.9.4.2.4.3, the technical description shall contain a warning to the effect of: "Warning: This device, when removed from its wall or ceiling mount, does not meet the stability requirements of IEC 80601-2-13 and IEC 60601-1 respectively. Special caution has to be taken." The technical description shall contain any additional handling instructions necessary to allow transport with an acceptable RISK according to the RISK MANAGEMENT FILE.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005, Clause 8 applies, except as follows:

201.8.11.3 POWER SUPPLY CORDS

Addition:

201.8.11.3.101 * Additional requirements for POWER SUPPLY CORDS

Unless the ANAESTHETIC WORKSTATION or its individual components automatically switch over to an INTERNAL ELECTRICAL POWER SOURCE (see 201.11.8.102) or the functionality of the complete ANAESTHETIC WORKSTATION can be restored in less than 30 s following the restoration of power, the POWER SUPPLY CORD of the ANAESTHETIC WORKSTATION or its individual components shall be a non-detachable cord or shall be protected against accidental disconnection.

Check compliance by inspection. For an ANAESTHETIC WORKSTATION and its individual components provided with an APPLIANCE COUPLER, subject the DETACHABLE POWER SUPPLY CORD to an axial pull of force for 1 min as shown in Table 201.102. During the test, the MAINS CONNECTOR shall not become disconnected from the APPLIANCE INLET, and the ME EQUIPMENT shall continue to function normally.

Table 201.102 — Force of axial pull

Mass (m) of ME EQUIPMENT kg	Pull force N
m ≤ 1	30
1 < m ≤ 4	60
m > 4	100

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 9 applies, except as follows:

201.9.2.1 General

Addition:

Where the direction of movement of a moving part needs to be known in order to avoid a HAZARDOUS SITUATION, the direction of movement shall be marked on the moving part or its housing.

Check compliance by inspection.

201.9.2 HAZARDS associated with moving parts

Addition:

201.9.2.101 Maintenance points

Any maintenance points shall be located outside DANGER ZONES and adjustment, maintenance, repair, cleaning and servicing operations shall be possible when the ANAESTHETIC WORKSTATION is not being operated.

Where this is not achievable, alternative means of RISK mitigation, e.g. alarming and information of safety and training, are permitted to reduce the RISK to acceptable levels.

Check compliance by inspection of the RISK MANAGEMENT FILE and USABILITY ENGINEERING FILE.

201.9.2.102 * Lighting

ANAESTHETIC WORKSTATIONS shall be supplied with lighting where the absence thereof causes an unacceptable RISK.

NOTE Attention is drawn to areas of shadows likely to cause nuisance, irritating dazzles, dangerous stroboscopic effects on moving parts, to internal parts requiring frequent inspection and adjustment, and to maintenance areas.

Check compliance by inspection of the RISK MANAGEMENT FILE and USABILITY ENGINEERING FILE.

201.9.2.103 * Integrated seating

Where a seat for the OPERATOR is an integral part of the ANAESTHETIC WORKSTATION, the seat shall

— enable the OPERATOR to maintain a stable position,

— be adaptable for the OPERATOR's distance from the control device,

— be adaptable for the OPERATOR, e.g. arm length, height, etc.,

— be designed to minimize transmission of vibrations to the OPERATOR,

— withstand maximum operational stresses, and

— be provided with slip-resistant footrests where no floor is underneath the OPERATOR.

Check compliance by functional testing.

201.9.2.104 * Arrangement of control positions

For ANAESTHETIC WORKSTATIONS which contain one or more DANGER ZONES

— the OPERATOR shall be able to ensure, from each control position, that no one is in the DANGER ZONE(S), or

— the control system shall be designed in such a way that starting is prevented while someone is in the DANGER ZONE, or

— an audible or visual ALARM SIGNAL shall be given long enough before the ANAESTHETIC WORKSTATION is started to allow anyone wholly or partially in a DANGER ZONE to leave the area.

Where there is more than one control position for an ANAESTHETIC WORKSTATION, the control systems shall be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When an ANAESTHETIC WORKSTATION has two or more operating positions, each position shall be provided with all the required control devices without the OPERATORS hindering or putting each other into a HAZARDOUS SITUATION.

Check compliance by visual inspection and functional testing.

201.9.4 Instability HAZARDS

IEC 60601-1:2005, 9.4 applies, except as follows:

201.9.4.2.4.3 Movement over a threshold

Amendment:

In the requirement replace the height of the threshold by 10 mm (instead of 20 mm) and in the test method replace the height of the solid vertical plane obstruction by 10 mm (instead of 20 mm).

ANAESTHETIC WORKSTATIONS that are intended only to be used when mounted to a wall or pendant, but may need to be removed from the wall or pendant for service or at initial installation, are not considered mobile equipment and the threshold test specified in IEC 60601-1:2005, 9.4.2.4.3 does not apply. Such non-mobile machines can use small casters to aid service and installation of the device. See also 201.7.9.3.102.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005, Clause 11 applies, except as follows:

201.11.6.3 SPILLAGE on ME EQUIPMENT and ME SYSTEMS

Replacement:

The ANAESTHETIC WORKSTATION and its individual components shall be so constructed that SPILLAGE does not wet parts which, when wetted, pose an unacceptable RISK.

Check compliance by the following test:

Test the ANAESTHETIC WORKSTATION and its individual components under the least favourable specified working conditions, but in accordance with the instructions for use. Pour a quantity of 200 ml of normal tap water steadily on an arbitrary point on the top surface of the ANAESTHETIC WORKSTATION and its individual components, for approximately 15 s, from a height not exceeding 5 cm. After the test, the ANAESTHETIC WORKSTATION and its individual components shall comply with all the requirements of this International Standard for NORMAL CONDITION.

201.11.6.8 Compatibility with substances used with the ME EQUIPMENT

Addition:

The ANAESTHETIC WORKSTATION and its individual components shall be designed and manufactured to minimize health RISKS due to substances leached or leaking from the ANAESTHETIC WORKSTATION or its individual components during NORMAL USE. Particular attention shall be paid to the toxicity of materials and their compatibility with substances and gases with which they come into contact during NORMAL USE.

NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction.

201.11.8 Interruption of the POWER SUPPLY/SUPPLY MAINS to ME EQUIPMENT

Addition:

201.11.8.101 * General requirements

The instructions for use shall describe the functioning of the ANAESTHETIC WORKSTATION or its individual components after interruption of the POWER SUPPLY, and where applicable following a switchover to an INTERNAL ELECTRICAL POWER SOURCE. Particular emphasis shall be placed on the flow rate and composition of the FRESH GAS and the behaviour of any OPERATOR-accessible gas POWER SUPPLY outlet under these circumstances.

Check compliance by inspection of the instructions for use.

201.11.8.102 * ALARM CONDITION for POWER SUPPLY failure

The ANAESTHETIC WORKSTATION shall be equipped with an ALARM SYSTEM that includes a POWER SUPPLY failure ALARM SIGNAL that indicates when the POWER SUPPLY is outside the range specified by the MANUFACTURER. The ALARM SIGNALS for the POWER SUPPLY failure ALARM CONDITION shall be

— generated for at least 7 s if pneumatically generated, or

— at least 5 bursts and a HIGH PRIORITY alarm that complies with IEC 60601-1-8, if electronically generated.

EXAMPLE The Ritchie Whistle is a pneumatic alarm sound generator.

NOTE 1 The POWER SUPPLY failure TECHNICAL ALARM CONDITION applies to the supply mains, an internal electrical power source or pneumatic (driving) power supply.

NOTE 2 The 7 s duration of the ALARM SIGNALS for the POWER SUPPLY failure ALARM CONDITION is measured exclusive of any INTERBURST INTERVAL.

The A-weighted sound pressure level shall be at least 2 dB above a white background sound level of 55 dB when tested as described in ISO 3746.

If the normal operation of the ANAESTHETIC WORKSTATION or its individual components is maintained by the automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE or alternate pneumatic POWER SUPPLY, the POWER SUPPLY failure HIGH PRIORITY TECHNICAL ALARM CONDITION shall not occur. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE or alternate pneumatic POWER SUPPLY shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.

Check compliance by functional testing.

201.11.8.103 * INTERNAL ELECTRICAL POWER SOURCE

If the ANAESTHETIC WORKSTATION or its individual components has/have an INTERNAL ELECTRICAL POWER SOURCE,

a) it/they shall be equipped with:

1) a means of determining the state of the INTERNAL ELECTRICAL POWER SOURCE; this means may be qualitative;

EXAMPLE 1 An indication of the remaining time provided by the INTERNAL ELECTRICAL POWER SOURCE.

EXAMPLE 2 An indication of the percentage of the remaining capacity provided by the INTERNAL ELECTRICAL POWER SOURCE.

EXAMPLE 3 A fuel gauge of the remaining capacity provided by the INTERNAL ELECTRICAL POWER SOURCE.

NOTE An uncalibrated fuel gauge that only indicates the state of the power source could be qualitative.

2) an ALARM SYSTEM that is equipped with a TECHNICAL ALARM CONDITION of at least MEDIUM PRIORITY that indicates when the INTERNAL ELECTRICAL POWER SOURCE nears depletion; this ALARM CONDITION shall occur prior to the loss of function;

EXAMPLE 4 A MEDIUM PRIORITY TECHNICAL ALARM CONDITION 5 min prior to the loss of all function.

b) the instructions for use shall include the following:

1) the operational time of the INTERNAL ELECTRICAL POWER SOURCE when fully charged;

2) the behaviour after a switchover to the INTERNAL ELECTRICAL POWER SOURCE;

3) the behaviour while the INTERNAL ELECTRICAL POWER SOURCE is recharging.

Check compliance by functional testing and inspection of the instructions for use.

201.11.101 Packaging systems for components intended to be sterilized

Packaging systems shall be designed to maintain components at their intended level of cleanliness and to reduce the RISK of microbial contamination.

Check compliance by inspection.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, Clause 12 applies, except as follows:

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 * Accidental adjustment of operating controls

A means of protection against accidental adjustment of operating controls that can create a HAZARDOUS SITUATION shall be provided. This includes the accidental turning off of the ANAESTHETIC WORKSTATION or its individual components.

If a selector switch or control is provided to change from one mode to another, it shall be bi-stable.

EXAMPLE 1 Requiring a confirmation step can be one method.

EXAMPLE 2 Manual/automatic ventilation selector switch, vaporiser selector switch, CIRCLE ABSORBER ASSEMBLY bypass mechanism.

The USABILITY of the means of protection shall be evaluated in the USABILITY ENGINEERING PROCESS according to IEC 60601-1-6.

Check compliance by functional testing and inspection of USABILITY ENGINEERING FILE.

201.12.4.102 * Additional requirements for ANAESTHETIC WORKSTATIONS

The ANAESTHETIC WORKSTATION shall be equipped with the following MONITORING EQUIPMENT, ALARM SYSTEMS, and PROTECTION DEVICES. If not so equipped, the instructions for use shall contain a statement to the effect that the ANAESTHETIC WORKSTATION is to be equipped with the following MONITORING EQUIPMENT, ALARM SYSTEMS, and PROTECTION DEVICES complying with this International Standard, before being put into service and shall describe how to connect these items:

— AIRWAY PRESSURE MONITORING EQUIPMENT complying with 201.12.4.109;

— MAXIMUM LIMITED PRESSURE PROTECTION DEVICE COMPLYING with 201.102.2.1 (ANAESTHETIC BREATHING SYSTEM) OR 201.105.2.1 (ANAESTHETIC ventilator);

— adjustable pressure limitation PROTECTION DEVICE complying with 201.102.2.2 (ANAESTHETIC BREATHING SYSTEM) or 201.105.2.2 (ANAESTHETIC VENTILATOR);

— exhaled volume MONITORING EQUIPMENT complying with 201.12.4.104;

— ALARM SYSTEM with ANAESTHETIC BREATHING SYSTEM integrity ALARM CONDITION complying with 201.12.4.105;

— carbon dioxide MONITORING EQUIPMENT complying with 201.12.4.103.1;

— oxygen MONITORING EQUIPMENT complying with 201.12.4.103.2;

— anaesthetic agent MONITORING EQUIPMENT with halogenated agent MONITORING EQUIPMENT if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM complying with 201.12.4.103.3;

— ANAESTHETIC BREATHING SYSTEM continuing-positive-pressure ALARM CONDITION complying with 201.12.106;

— oxygen supply failure ALARM SYSTEM and PROTECTION DEVICE complying with 201.12.4.107.1 and 201.12.4.107.2 respectively;

— hypoxic mixture delivery selection PROTECTION DEVICE complying with 201.12.4.107.3;

— PROTECTION DEVICE for the workplace environment (ANAESTHETIC GAS SCAVENGING SYSTEM) if the ANAESTHETIC GAS DELIVERY SYSTEM IS equipped with means to deliver nitrous oxide or is designed to be equipped with AN ANAESTHETIC VAPOUR DELIVERY SYSTEM complying with 201.12.4.108.

MANUFACTURERS of individual components shall make available information regarding how to connect these items to the ANAESTHETIC WORKSTATION.

Check compliance by inspection and, if applicable, inspection of the instructions for use.

NOTE See also Table AA.1.

201.12.4.103 Respiratory gas MONITORING EQUIPMENT

201.12.4.103.1 Carbon dioxide MONITORING EQUIPMENT

Carbon dioxide MONITORING EQUIPMENT shall comply with ISO/IEC 80601-2-55.

Check compliance by application of the tests of ISO/IEC 80601-2-55.

201.12.4.103.2 Oxygen MONITORING EQUIPMENT

Oxygen MONITORING EQUIPMENT shall comply with ISO/IEC 80601-2-55.

Check compliance by application of the tests of ISO/IEC 80601-2-55.

201.12.4.103.3 Anaesthetic agent MONITORING EQUIPMENT

If the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM the ANAESTHETIC WORKSTATION shall be equipped with halogenated anaesthetic agent MONITORING EQUIPMENT. If not so equipped, the instructions for use of the ANAESTHETIC GAS DELIVERY SYSTEM shall contain a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with halogenated anaesthetic agent MONITORING EQUIPMENT complying with ISO/IEC 80601-2-55 before the ANAESTHETIC WORKSTATION is put into service; also, it shall describe how to connect it.

MANUFACTURERS of halogenated anaesthetic agent MONITORING EQUIPMENT shall make information regarding how to connect that item to the ANAESTHETIC WORKSTATION available upon request.

Check compliance by inspection of the instructions for use or application of the tests of ISO/IEC 80601-2-55.

201.12.4.104 Exhaled volume MONITORING EQUIPMENT

201.12.4.104.1 * Accuracy

For displayed tidal volume above 100 ml the accuracy shall be ±20 % of actual reading; for displayed minute volume above 1 l/min the accuracy shall be ±20 % of actual reading. The accuracy of the displayed exhaled volume MONITORING EQUIPMENT below these levels shall be disclosed in the instructions for use.

Check compliance with the following tests and, if applicable, by inspection of the instructions for use.

Connect the ANAESTHETIC BREATHING SYSTEM to a test lung, ventilate the test lung under the appropriate conditions described in Table 201.103 using oxygen and dry until measured exhaled volumes are stable.

Table 201.103 — Test conditions for expiratory volume tests

Expiratory volume range	Adjustable parameter				
	C	R	V_T	f	I/E
V_T > 300 ml	500 ± 5 %	0,5 ± 10 %	500	10	1:1,5 to 1:2,5
300 ml ≥ V_T >50 ml	200 ± 5 %	2 ± 10 %	300	20	1:1,0 to 1:1,5
V_T ≤ 50 ml	10 ± 5 %	5 ± 10 %	30	30	1:1,0 to 1:1,5

C = Compliance in ml/kPa.

R = Resistance in kPa/l/s.

V_T = Tidal volume in millilitres; V_T is derived from pressure sensor on test lung.

[V_T = C multiplied by end inspiratory pressure – positive end-expiratory pressure (PEEP)].

f = Frequency in breaths per minute.

I/E = the ratio of the inspiratory time to the expiratory time.

NOTE The tolerances for C and R apply over the ranges of the measured parameters.

201.12.4.104.2 ALARM CONDITIONS

The exhaled volume MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that includes a PHYSIOLOGICAL ALARM CONDITION of at least MEDIUM PRIORITY that indicates when the PATIENT'S exhaled volume falls below an OPERATOR-adjustable ALARM LIMIT. If the ALARM SIGNAL can be delayed, the ALARM SIGNAL GENERATION DELAY shall not exceed 90 s. The ALARM SIGNAL GENERATION DELAY may be OPERATOR-adjustable.

Check compliance by functional testing.

201.12.4.105 * ANAESTHETIC BREATHING SYSTEM integrity ALARM CONDITION

The ANAESTHETIC BREATHING SYSTEM integrity ALARM CONDITION shall indicate when the ANAESTHETIC BREATHING SYSTEM has significant leakage, including disconnection, and shall be of at least MEDIUM PRIORITY. The ANAESTHETIC BREATHING SYSTEM integrity ALARM CONDITION may be indicated by other ALARM CONDITIONS including low AIRWAY PRESSURE, low or zero exhaled carbon dioxide or low exhaled volume.

NOTE The ALARM SYSTEM indicates specific ALARM CONDITIONS and does not necessarily differentiate between possible causes.

Check compliance by functional testing.

201.12.4.106 * ANAESTHETIC BREATHING SYSTEM continuing-positive-pressure ALARM CONDITION

The ANAESTHETIC BREATHING SYSTEM shall be equipped with an ALARM SYSTEM that includes an ALARM CONDITION that indicates when the AIRWAY PRESSURE exceeds the continuing positive pressure ALARM LIMIT. If not so equipped, the instructions for use of the ANAESTHETIC BREATHING SYSTEM shall contain a statement to the effect that the ANAESTHETIC BREATHING SYSTEM is to be provided with an ALARM SYSTEM that includes an ALARM CONDITION that indicates when the AIRWAY PRESSURE exceeds the continuing positive pressure ALARM LIMIT before the ANAESTHETIC BREATHING SYSTEM is put into service. Unless the ALARM SYSTEM that includes an ALARM CONDITION that indicates when the AIRWAY PRESSURE exceeds the continuing positive pressure ALARM LIMIT is an integral part of the ANAESTHETIC BREATHING SYSTEM, information on how to connect it shall be disclosed in the instructions for use of the ANAESTHETIC BREATHING SYSTEM.

The maximum ALARM CONDITION DELAY shall not exceed 17 s or two breath cycles, whichever is longer. The ANAESTHETIC BREATHING SYSTEM continuing positive pressure ALARM CONDITION shall be at least MEDIUM PRIORITY. The ANAESTHETIC BREATHING SYSTEM continuing positive pressure ALARM LIMIT may be OPERATOR-adjustable.

Check compliance by functional testing and, if applicable, inspection of the instructions for use.

201.12.4.107 ANAESTHETIC GAS DELIVERY SYSTEM oxygen supply and delivery

201.12.4.107.1 Oxygen supply failure ALARM SYSTEM

The ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with an ALARM SYSTEM that includes a HIGH PRIORITY TECHNICAL ALARM CONDITION that indicates when the oxygen supply, whether derived from a MEDICAL GAS PIPELINE SYSTEM or from a cylinder, is about to fall, or has already fallen, below a value necessary for normal operation.

A pneumatically generated auditory ALARM SIGNAL may be used. A pneumatically generated auditory ALARM SIGNAL shall be at least 7 s in duration, and when tested as described in ISO 3746, its A-weighted sound pressure level shall be at least 2 dB above a white background sound level of 55 dB. A pneumatically generated ALARM SIGNAL shall derive its energy from the oxygen supply source.

EXAMPLE “Ritchie whistle”.

Check compliance by functional testing.

201.12.4.107.2 * Oxygen supply failure PROTECTION DEVICE

The ANAESTHETIC GAS DELIVERY SYSTEM shall be provided with an oxygen supply failure PROTECTION DEVICE that activates whenever the oxygen supply has fallen below a value necessary for normal operation.

EXAMPLE Nitrous oxide cut-off.

The oxygen supply failure PROTECTION DEVICE shall

— cut off the supply of all gases other than oxygen, air and premixed gases with an oxygen content above ambient to the FRESH-GAS OUTLET, or

— progressively reduce the flow rate of all other gases (except air or premixed gases with an oxygen content above ambient) while maintaining the proportion of oxygen until the supply of oxygen finally fails. When the supply of oxygen fails, the supply of all other gases (except air or premixed gases with an oxygen content above ambient) shall be cut off.

The behaviour of the ANAESTHETIC GAS DELIVERY SYSTEM under these conditions shall be disclosed in the instructions for use.

Check compliance by inspection of the instructions for use and by functional testing.

201.12.4.107.3 * Hypoxic mixture delivery selection PROTECTION DEVICE

The ANAESTHETIC GAS DELIVERY SYSTEM shall be provided with a PROTECTION DEVICE to prevent the unintentional selection of a mixture of oxygen/nitrous oxide or a mixture of oxygen/xenon having an oxygen concentration below that of ambient air.

When a mixture of gases having an oxygen concentration below 19 % is selected, a CLEARLY LEGIBLE indication shall be continuously provided.

EXAMPLE INFORMATION SIGNAL or LOW PRIORITY ALARM SIGNAL indicating presence of override mode.

Check compliance by visual inspection and by functional testing.

201.12.4.108 * PROTECTION DEVICE for the workplace environment

If the ANAESTHETIC GAS DELIVERY SYSTEM is equipped with means to deliver nitrous oxide or is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM, the ANAESTHETIC WORKSTATION shall be equipped with an ANAESTHETIC GAS SCAVENGING SYSTEM as a PROTECTION DEVICE. If not so equipped, the instructions for use for the ANAESTHETIC WORKSTATION shall contain a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with an ANAESTHETIC GAS SCAVENGING SYSTEM complying with this International Standard before being put into service. The instructions for use of the ANAESTHETIC WORKSTATION and the ANAESTHETIC GAS SCAVENGING SYSTEM shall disclose how to connect the ANAESTHETIC GAS SCAVENGING SYSTEM.

MANUFACTURERS of the ANAESTHETIC GAS SCAVENGING SYSTEM shall make information regarding how to connect that item to the ANAESTHETIC WORKSTATION available upon request.

Check compliance by inspection of the instructions for use.

201.12.4.109 AIRWAY PRESSURE MONITORING EQUIPMENT

The ANAESTHETIC WORKSTATION shall be equipped with AIRWAY PRESSURE MONITORING EQUIPMENT. If not so equipped, the instructions for use of the ANAESTHETIC WORKSTATION, the ANAESTHETIC BREATHING SYSTEM (if supplied separately) and the ANAESTHETIC VENTILATOR (if supplied separately), shall contain a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with AIRWAY PRESSURE MONITORING EQUIPMENT complying with this International Standard before being put into service; also, it shall describe how to connect that item. MANUFACTURERS of the AIRWAY PRESSURE MONITORING EQUIPMENT shall make available on request information on how to connect that item to the ANAESTHETIC WORKSTATION, the ANAESTHETIC BREATHING SYSTEM and the ANAESTHETIC VENTILATOR.

The AIRWAY PRESSURE MONITORING EQUIPMENT shall include an ALARM SYSTEM that generates an ALARM CONDITION of at least MEDIUM PRIORITY to indicate when the AIRWAY PRESSURE exceeds an OPERATOR-adjustable high pressure ALARM LIMIT.

If the ALARM SYSTEM generates an ALARM CONDITION upon a failure to reach an OPERATOR-adjustable minimum pressure threshold, that ALARM CONDITION shall be of at least MEDIUM PRIORITY.

NOTE The failure to reach an OPERATOR-adjustable minimum pressure threshold ALARM CONDITION can act as a "failure to cycle" ALARM CONDITION.

The AIRWAY PRESSURE MONITORING EQUIPMENT shall have a minimum range from 10 hPa (10 cmH_2O) below ambient pressure to 60 hPa (60 cmH_2O) above ambient pressure or to the MAXIMUM LIMITED PRESSURE, whichever is greater.

The AIRWAY PRESSURE MONITORING EQUIPMENT shall be accurate within a tolerance of ± (2 % of the full scale reading + 4 % of the reading).

The AIRWAY PRESSURE MONITORING EQUIPMENT should include an ALARM SYSTEM that generates an ALARM CONDITION of at least MEDIUM PRIORITY to indicate when the AIRWAY PRESSURE falls below an OPERATOR-adjustable ALARM LIMIT.

Check compliance by functional testing and, if applicable, by inspection of the instructions for use.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005, Clause 13 applies, except as follows:

Addition:

201.13.101 * Simultaneous failure

A SINGLE FAULT CONDITION shall not cause the simultaneous failure of a control function and

— its associated MONITORING EQUIPMENT or ALARM SYSTEM, or

— its associated PROTECTION DEVICE.

Check compliance by inspection or functional testing.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005, Clause 14 applies, except as follows:

201.14.6.1 * Identification of known and foreseeable HAZARDS

Amendment (add at the end of the subclause):

The ANAESTHETIC WORKSTATION and its individual components which incorporate radiofrequency (RF) wireless technology should be assessed for the following RISKS:

— performance of wireless functions;

— wireless coexistence;

— wireless quality of service;

— integrity of data transmitted wirelessly;

— security of data transmitted wirelessly;

— wireless network access.

Addition:

201.14.101 Software life cycle PROCESSES

PROGRAMMABLE ELECTRONIC SUB-SYSTEMS (PESS) of an ANAESTHETIC WORKSTATION and its individual components shall be developed with an IEC 62304 compliant design PROCESS. Ventilation control, gas mixture control, and vapour delivery SOFTWARE ITEMS of PESS without an independent RISK CONTROL measure shall be considered as software safety Class C.

EXAMPLE Independent hardware or software measure.

Check compliance by inspection of the documentation required by IEC 62304 for the software safety class (see IEC 62304:2006, 1.4).

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005, Clause 15 applies.

201.16 ME SYSTEMS

IEC 60601-1:2005, Clause 16 applies, except as follows:

201.16.9.2.1 MULTIPLE SOCKET-OUTLETS

Amendment:

Delete the second dash of 16.9.2.1 a) and add the following text under the last list item in 16.9.2.1 a):

An ANAESTHETIC WORKSTATION may provide MULTIPLE SOCKET-OUTLETS that can accept standard MAINS PLUGS of the kind specified in IEC/TR 60083.

Addition:

Add the following list item:

ee) The ANAESTHETIC WORKSTATION and each MULTIPLE SOCKET-OUTLET which can accept a standard MAINS PLUG shall be provided with separate fuses or over-current releases as required for a single piece of ME EQUIPMENT in IEC 60601-1:2005, 8.11.5.

These fuses or over-current releases shall be designed such that the ANAESTHETIC WORKSTATION including the MULTIPLE SOCKET-OUTLETS maintain normal function with each MULTIPLE SOCKET-OUTLET loaded to the maximum rating.

If any MULTIPLE SOCKET-OUTLET is overloaded by a factor of $7,5 \pm 2,5$, all remaining MULTIPLE SOCKET-OUTLETS and the ANAESTHETIC WORKSTATION shall maintain normal function.

Check compliance by visual inspection and functional testing.

Addition:

201.16.101 Additional requirements for SIGNAL INPUT/OUTPUT PART

201.16.101.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained during the failure of equipment connected to a SIGNAL INPUT/OUTPUT PART of the ANAESTHETIC WORKSTATION or its individual components or the disruptions of such connections.

Check compliance by functional testing.

201.16.101.2 Connection to electronic health record

An ANAESTHETIC WORKSTATION or its individual components may be equipped with a SIGNAL INPUT/OUTPUT PART that permits data transmission from the ANAESTHETIC WORKSTATION or its components to an electronic health record.

201.16.101.3 Connection to DISTRIBUTED ALARM SYSTEM

An ANAESTHETIC WORKSTATION or its individual components may be equipped with a SIGNAL INPUT/OUTPUT PART for connection to a DISTRIBUTED ALARM SYSTEM.

201.16.101.4 * Connection for remote control

An ANAESTHETIC WORKSTATION may be equipped with a SIGNAL INPUT/OUTPUT PART for connection for remote control of the ANAESTHETIC WORKSTATION.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 17 applies.

New clauses:

201.101 Additional requirements for ANAESTHETIC GAS DELIVERY SYSTEMS

201.101.1 Identification and documents

201.101.1.1 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM complies with this International Standard;

b) unless the ANAESTHETIC BREATHING SYSTEM is integral to the ANAESTHETIC GAS DELIVERY SYSTEM or ANAESTHETIC WORKSTATION, a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM or ANAESTHETIC WORKSTATION is intended to be used with an ANAESTHETIC BREATHING SYSTEM that complies with this International Standard;

c) instructions for testing for correct assembly and connection of each gas supply;

d) if applicable, the medical gas supply pressure(s) at which the ANAESTHETIC GAS DELIVERY SYSTEM will cease to deliver gas as specified;

e) unless the ANAESTHETIC BREATHING SYSTEM is an integral part of the ANAESTHETIC GAS DELIVERY SYSTEM, information on how to connect an ANAESTHETIC BREATHING SYSTEM;

f) if the ANAESTHETIC GAS DELIVERY SYSTEM is equipped with a means to deliver nitrous oxide or is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM is to be used with an ANAESTHETIC GAS SCAVENGING SYSTEM complying with this International Standard;

g) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM used with the ANAESTHETIC GAS DELIVERY SYSTEM shall comply with this International Standard;

h) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM is to be used with halogenated anaesthetic agent MONITORING EQUIPMENT complying with ISO/IEC 80601-2-55;

i) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VENTILATOR, a statement to the effect that the ANAESTHETIC VENTILATOR shall comply with the requirements of this International Standard;

j) a statement to the effect that the ANAESTHETIC WORKSTATION is intended for use with non-flammable anaesthetic agents as specified in this International Standard and that flammable anaesthetic agents such as diethyl ether and cyclopropane are not to be used in the ANAESTHETIC WORKSTATION.

NOTE Annex BB contains the criteria for determining when an anaesthetic agent is non-flammable.

Check compliance by inspection of the instructions for use.

201.101.1.2 Technical description

The technical description shall include the following:

a) pressure and flow rate characteristics of any gas POWER SUPPLY outlet throughout the RATED range of inlet pressure;

b) operating characteristics and location of any pressure relief PROTECTION DEVICES.

Check compliance by inspection of the technical description.

201.101.2 * Interruption of the electrical POWER SUPPLY

The ANAESTHETIC GAS DELIVERY SYSTEM shall be so designed that in the event of an electrical POWER SUPPLY failure, either the supply of FRESH GAS is unaffected or an alternative means of gas delivery is available.

Check compliance by inspection and functional testing.

201.101.3 Protection against cross-contamination of volatile anaesthetic agents

If an ANAESTHETIC GAS DELIVERY SYSTEM provides connectors for more than one ANAESTHETIC VAPOUR DELIVERY SYSTEM, a means shall be provided to prevent contamination of the contents of one ANAESTHETIC VAPOUR DELIVERY SYSTEM with another volatile anaesthetic agent.

EXAMPLE Interlock system allowing the operation of only one vaporizer at a time.

See also 201.104.5.

Check compliance by inspection and functional testing.

201.101.4 Medical gas supply

201.101.4.1 Cylinder supplies

201.101.4.1.1 Inlet connector

Connections to medical gas cylinders shall comply with ISO 407 or ISO 5145.

Check compliance by application of the tests of ISO 407 or ISO 5145.

201.101.4.1.2 Inlet filtration

Each medical gas supply inlet connection shall be equipped with a means to prevent particles greater than 100 µm from entering the ANAESTHETIC GAS DELIVERY SYSTEM. The location at which the supply pressure is monitored (see 201.101.4.3) shall be downstream of the filter.

Check compliance by inspection.

201.101.4.1.3 Pressure regulators

PRESSURE REGULATORS that are integral parts of the ANAESTHETIC GAS DELIVERY SYSTEM intended for use at inlet pressures >1 400 kPa shall comply with ISO 10524-1:2006, 5.3, 5.5.1, 5.4.8 and 5.4.11.

Check compliance by application of the tests of ISO 10524-1.

201.101.4.1.4 * Reserve oxygen supply

The ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with a means of connecting to a reserve oxygen supply.

Check compliance by inspection.

201.101.4.2 Pipeline supplies

201.101.4.2.1 Inlet connector

Pipeline inlet connectors for the ANAESTHETIC GAS DELIVERY SYSTEM shall be one of the following:

a) male non-interchangeable screw-threaded (NIST) connector, or

b) female diameter-index safety system (DISS) connector, or

c) male sleeve index system (SIS)

as specified in ISO 5359.

NOTE National or regional regulations may specify a particular connector.

Check compliance by inspection.

201.101.4.2.2 Inlet filtration

Each medical gas supply inlet connection shall be equipped with a means to prevent particles greater than 100 µm from entering the ANAESTHETIC GAS DELIVERY SYSTEM. The location at which the supply pressure is monitored (see 201.101.4.3) shall be downstream of the filter.

Check compliance by inspection.

201.101.4.2.3 Reverse flow and cross-flow PROTECTION DEVICE

The ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with a cross-flow PROTECTION DEVICE to limit, under NORMAL CONDITION:

— the reverse gas flow rate between gas input ports of the same gas to 100 ml/min (169 Pa x l/s);

— the flow rate of gas from one input port to an input port of a different gas to less than 10 ml/h (0,281 Pa x l/s).

If under SINGLE FAULT CONDITION the flow rate of gases between input ports of different gases can exceed 10 ml/h (0,281 Pa x l/s), the ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with a means to indicate this unacceptable RISK, for example, by means of an ALARM SIGNAL.

Check compliance by functional testing.

201.101.4.3 Pressure or content MONITORING EQUIPMENT

The ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with pressure or content MONITORING EQUIPMENT for each gas supplied from a MEDICAL GAS PIPELINE SYSTEM or at cylinder pressure. The MONITORING EQUIPMENT shall display the pressure or content for each gas continuously or on OPERATOR demand. This display shall be visible from the front of the ANAESTHETIC GAS DELIVERY SYSTEM.

NOTE In a cylinder with liquefied gas, cylinder pressure does not reflect cylinder contents.

The maximum error of the MONITORING EQUIPMENT shall not exceed ± (4 % of the full scale reading + 8 % of the actual reading).

Check compliance by inspection and functional testing.

201.101.5 ANAESTHETIC GAS DELIVERY SYSTEM leakage

201.101.5.1 Leakage prior to the flow rate adjustment control element

Except for the venting of air or oxygen from fluidic or pneumatic elements, the gas leakage from that part of the ANAESTHETIC GAS DELIVERY SYSTEM PIPING up to the inlet of the flow rate adjustment control part, and the piping between the inlet connections for cylinders and PRESSURE REGULATORS, shall not exceed 75 ml/min (7,599 kPa x l/min) when it is pressurized to the maximum design pressure.

NOTE This requirement allows 25 ml/min (2,533 kPa x l/min) leakage, each, for the cylinder attachment, the PRESSURE REGULATOR assembly and the ANAESTHETIC GAS DELIVERY SYSTEM PIPING.

Check compliance by functional testing.

201.101.5.2 Leakage after the flow rate adjustment control element

The gas leakage to atmosphere between the outlet of the flow rate adjustment control or gas mixer and the FRESH-GAS OUTLET shall not exceed 50 ml/min (5,065 kPa x l/min) at a pressure of 30 hPa (30 cmH_2O).

NOTE An ANAESTHETIC GAS DELIVERY SYSTEM can permit a continuous basal flow of oxygen. This should not be confused with leakage to atmosphere.

This requirement shall be met with any ANAESTHETIC VAPOUR DELIVERY SYSTEM specified in the instructions for use when the ANAESTHETIC VAPOUR DELIVERY SYSTEM is

— on,

— off, and

— removed, if it is OPERATOR-detachable.

Check compliance by functional testing.

201.101.6 Gas flow rate metering

201.101.6.1 Graduations and accuracy

All FLOWMETERS or flow rate adjustment controls shall be graduated in litres per minute (l/min).

For flow rates of 1 l/min or below, the flow rate shall be expressed either in millilitres per minute (ml/min) or in decimal fractions of litres per minute (l/min) (with a zero before the decimal marker). The method of graduation shall be consistent on any one ANAESTHETIC GAS DELIVERY SYSTEM.

The accuracy of the graduations of any FLOWMETER or flow rate adjustment control used in the ANAESTHETIC GAS DELIVERY SYSTEM shall be within ±10 % of the indicated value for flow rates between 10 % and 100 % of full scale when discharged into the ambient atmosphere (see 201.5.101.2).

Check compliance by inspection and functional testing.

201.101.6.2 Flow rate adjustment control

Separate flow rate adjustment controls for each gas, if provided, shall meet the following requirements:

— there shall not be more than one flow rate adjustment control for any single gas delivered to the FRESH-GAS OUTLET under NORMAL CONDITION;

NOTE 1 An ANAESTHETIC GAS DELIVERY SYSTEM can incorporate an emergency oxygen flow rate adjustment control in addition to the normal oxygen flow rate adjustment control or gas mixer. Such an emergency oxygen flow rate adjustment control is designed for emergency use only, e.g. failure of an electronic controlled gas mixer or flow rate controller.

NOTE 2 A device that prevents delivery of oxygen at levels below those found in ambient air is not considered to be a flow rate adjustment control.

— a rotary style flow rate adjustment control for oxygen shall have a physical profile in accordance with Figure 201.102 and shall have a diameter not less than the diameter of the knobs controlling all other gases;

— all rotary style flow rate adjustment control knobs for gases other than oxygen shall be round and their surface serration shall not exceed a depth of 1 mm;

— an anticlockwise rotation of all rotary style flow rate adjustment control knobs shall cause an increase in flow rate and, conversely, a clockwise rotation shall cause a decrease in flow rate.

NOTE 3 Attention is drawn to the fact that the requirement in this subclause may be contrary to the convention for direction of rotation for electronic controls.

The oxygen FLOWMETER shall be positioned at either end of any bank of FLOWMETERS.

Check compliance by inspection.

Dimensions in millimetres

Figure 201.102 — Profile of an oxygen flow rate adjustment control knob

201.101.6.3 * Carbon dioxide flow rate adjustment control

If carbon dioxide is one of the gases that the ANAESTHETIC GAS DELIVERY SYSTEM can deliver, delivery of carbon dioxide shall be limited to a maximum of 600 ml/min.

Check compliance by inspection and functional testing.

201.101.7 Gas mixers

At any flow rate and pressure given in NORMAL USE, the oxygen concentration shall be within ±5 % volume fraction of the set or indicated value.

Check compliance by inspection and functional testing.

201.101.8 * Oxygen flush

The ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with a means to allow the OPERATOR to supply oxygen at a steady flow rate of between 25 l/min and 75 l/min directly to the FRESH-GAS OUTLET or inlet of the ANAESTHETIC BREATHING SYSTEM.

The oxygen flush shall have only one "OFF" position. The oxygen flush shall be operable with one hand and shall be self-closing.

It is recommended that the oxygen flush be located such that unintentional operation by equipment or personnel is prevented.

Means to supply any single gas other than oxygen directly to the FRESH-GAS OUTLET or to the inlet of the ANAESTHETIC BREATHING SYSTEM shall not be provided.

Check compliance by inspection, functional testing, and inspection of the USABILITY ENGINEERING FILE.

201.101.9 * FRESH-GAS OUTLET

If an OPERATOR-accessible FRESH-GAS OUTLET is provided, there shall be not more than one functional FRESH-GAS OUTLET. The FRESH-GAS OUTLET shall be a coaxial 22 mm/15 mm conical connector complying with ISO 5356-1 or ISO 5356-2.

Check compliance by inspection and application of the tests of ISO 5356-1 and ISO 5356-2.

201.102 Additional requirements for an ANAESTHETIC BREATHING SYSTEM

201.102.1 Identification, marking and documents

201.102.1.1 Marking

201.102.1.1.1 Non-metallic components

Non-metallic components of an ANAESTHETIC BREATHING SYSTEM or its components that are made of antistatic or conductive materials, and the packaging of such components, shall be marked with the CLEARLY LEGIBLE word “antistatic” or “conductive” or the equivalent in a language that is acceptable to the intended OPERATOR. These non-metallic components may additionally bear an indelible yellow coloured mark.

Check compliance by inspection.

201.102.1.1.2 Bag/ventilator control

An OPERATOR-controlled mechanism that changes from reservoir bag to ANAESTHETIC VENTILATOR and vice-versa, if provided, shall be marked with the words “bag” and “ventilator” or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol.

Check compliance by inspection.

201.102.1.1.3 Absorbent bypass

An OPERATOR-controlled mechanism for excluding the absorbent from the gas pathway shall be marked with the following:

— the words “on” and “off” or the equivalent in a language that is acceptable to the intended OPERATOR; or

— the words “absorber on” and “absorber off” or the equivalent in a language that is acceptable to the intended OPERATOR; or

— the symbols shown in Figure 201.103.

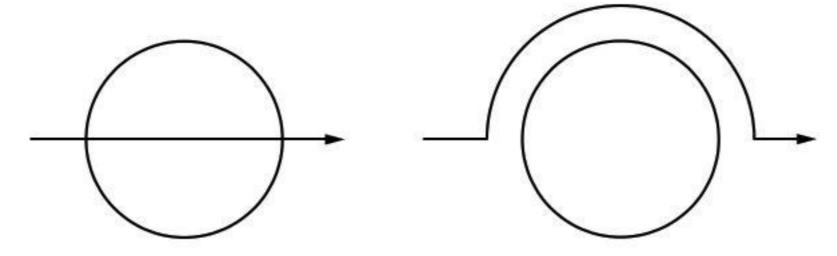
Check compliance by inspection.

a) Symbol for marking “on” **b) Symbol for marking “off”**

Figure 201.103 — Absorbent bypass control markings

201.102.1.1.4 Inspiratory and expiratory ports of a CIRCLE ABSORBER ASSEMBLY

The inspiratory and expiratory ports of a CIRCLE ABSORBER ASSEMBLY shall be marked with an arrow to indicate the intended direction of gas flow.

Check compliance by inspection.

201.102.1.2 Instructions for use

The instructions for use of an ANAESTHETIC BREATHING SYSTEM and its components shall include the following:

a) a diagram of the complete ANAESTHETIC BREATHING SYSTEM identifying its components and their recommended location(s);

b) a statement to the effect that the ANAESTHETIC BREATHING SYSTEM or its components comply with this International Standard;

c) unless the ANAESTHETIC BREATHING SYSTEM is an integral part of the ANAESTHETIC GAS DELIVERY SYSTEM or ANAESTHETIC WORKSTATION, information on how to connect an ANAESTHETIC BREATHING SYSTEM;

d) the internal compliance, expressed as a volume in millilitres (ml) at a pressure of 30 hPa (30 cmH_2O), with any reservoir bag excluded;

e) unless permanently mounted, the recommended orientation of the ANAESTHETIC BREATHING SYSTEM and its components and details of the effects of other orientations on performance;

EXAMPLE Water trap, EXHAUST VALVE.

f) information on any means of pressure relief, including pressure/flow-rate characteristics;

g) a statement of known compatibility with gases and anaesthetic agents;

h) a statement regarding the suitability for use with flammable anaesthetic agents, i.e. CATEGORY AP or CATEGORY APG;

i) instructions for use of ANAESTHETIC BREATHING SYSTEM components not integrated into the ANAESTHETIC BREATHING SYSTEM, which shall include a diagram showing the recommended locations of such ANAESTHETIC BREATHING SYSTEM components, the location of the FRESH-GAS INLET and the ventilator inlet;

j) instructions for use of EXHAUST VALVES not integrated into the ANAESTHETIC BREATHING SYSTEM, which shall describe the pressure/flow-rate characteristics of the EXHAUST VALVE including the opening pressure and the pressure drop at a flow rate of 30 l/min at BTPS;

k) instructions for use of a CIRCLE ABSORBER ASSEMBLY and its components not integrated into the ANAESTHETIC BREATHING SYSTEM, which shall identify the carbon dioxide absorbent recommended for use and the volume of the absorbent container expressed in millilitres (ml);

l) for breathing ACCESSORIES intended to be assembled by the OPERATOR, the resistance and compliance of those ACCESSORIES;

m) for an ANAESTHETIC BREATHING SYSTEM supplied separately, a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with an AIRWAY PRESSURE MONITORING EQUIPMENT complying with this International Standard (see 201.12.4.109) before being put into service and a description on how to connect that item.

Check compliance by inspection of the instructions for use.

201.102.2 Pressure limitation PROTECTION DEVICE

NOTE The ANAESTHETIC WORKSTATION is expected to have one MAXIMUM LIMITED PRESSURE PROTECTION DEVICE and one adjustable pressure limitation PROTECTION DEVICE which can be located either in the ANAESTHETIC BREATHING SYSTEM or in the ANAESTHETIC VENTILATOR (see 201.102.2.1, 201.102.2.2, 201.105.2.1 and 201.105.2.2).

201.102.2.1 * MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

The pressure at the PATIENT CONNECTION PORT shall be limited by a PROTECTION DEVICE to less than 125 hPa (125 cmH_2O) in NORMAL CONDITION and SINGLE FAULT CONDITION. A reservoir bag complying with ISO 5362 may be used for the SINGLE FAULT CONDITION pressure limitation PROTECTION DEVICE for an ANAESTHETIC WORKSTATION without an ANAESTHETIC VENTILATOR, or when the ANAESTHETIC VENTILATOR is in a manual or spontaneous ventilation mode.

NOTE The pressure limitation effect of a reservoir bag complying with ISO 5362 has a NOMINAL value of 55 hPa (55 cmH_2O).

Check compliance by functional testing.

201.102.2.2 * ADJUSTABLE PRESSURE LIMITATION PROTECTION DEVICE

The ANAESTHETIC BREATHING SYSTEM shall be equipped with a PROTECTION DEVICE to limit the pressure at the PATIENT CONNECTION PORT. This PROTECTION DEVICE shall ensure the pressure at the PATIENT CONNECTION PORT does not exceed the maximum OPERATOR-settable value by more than 10 hPa (10 cmH_2O) or 15 %, whichever is greater, in NORMAL CONDITION.

Check compliance by functional testing.

201.102.3 ANAESTHETIC BREATHING SYSTEM component packaging

ANAESTHETIC BREATHING SYSTEM components shall be packaged in such a way as to reduce the RISK of the incomplete removal of the packaging before use to acceptable levels.

NOTE This is to prevent accidental retention of the packaging, e.g. transparent wrapper, caps, lids, covers, and to ensure its removal by the OPERATOR prior to use.

Check compliance by inspection of the RISK MANAGEMENT FILE or USABILITY ENGINEERING FILE.

201.102.4 * Electrical conductivity

An ANAESTHETIC BREATHING SYSTEM or its components marked as “antistatic” or “conductive” shall have a maximum electrical resistance of 1,0 MΩ when tested according to ISO 2878.

When evaluating tubing, the resistance limit should be considered to be 1,0 MΩ/m.

Check compliance by inspection and application of the tests of ISO 2878.

201.102.5 Connection ports

201.102.5.1 PATIENT CONNECTION PORT

The PATIENT CONNECTION PORT shall be a coaxial 22 mm male/15mm female conical connector complying with ISO 5356-1. The PATIENT CONNECTION PORT may swivel.

Check compliance by inspection and application of the test of ISO 5356-1.

201.102.5.2 EXHAUST PORT connector

If an EXHAUST PORT connector is OPERATOR-detachable without the use of a TOOL, it shall be

a) marked with the word "exhaust" or "AGS" or the equivalent in a language that is acceptable to the intended OPERATOR, or an appropriate symbol, and

b) one of the following:

   1) for ANAESTHETIC BREATHING SYSTEMS intended to be OPERATOR-detachable without the use of a TOOL to an ANAESTHETIC GAS SCAVENGING SYSTEM, a 30 mm male conical connector complying with ISO 5356-1 with a means to prevent connection of the orifice to any ANAESTHETIC BREATHING SYSTEM port or component, or

   2) a proprietary connector that is incompatible with connectors complying with ISO 5356-1 and BREATHING TUBES complying with ISO 5367.

Check compliance by inspection, functional testing and application of the tests in ISO 5356-1 and ISO 5367.

201.102.5.3 * Reservoir bag connection port

The reservoir bag connection port, if provided, shall be compatible with a reservoir bag complying with ISO 5362 and a BREATHING TUBE complying with ISO 5367. This connection shall be within 20° of the vertical axis. The reservoir connection port shall not be on the PATIENT side of the inspiratory or expiratory valve(s).

The reservoir bag connection port shall be marked with the word "bag" or the equivalent in a language that is acceptable to the intended OPERATOR, or an appropriate symbol.

Check compliance by inspection, functional testing and application of the tests of ISO 5362 and ISO 5367.

201.102.5.4 ANAESTHETIC VENTILATOR port connector

If the ANAESTHETIC VENTILATOR port connector is OPERATOR-detachable without the use of a TOOL, it shall be:

a) marked with the word "ventilator" or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol;

b) a 22 mm male conical connector complying with ISO 5356-1 or ISO 5356-2.

Any other ANAESTHETIC VENTILATOR port connector shall be a proprietary fitting incompatible with connectors complying with ISO 5356-1 and BREATHING TUBES complying with ISO 5367.

Check compliance by inspection, functional testing and application of the tests of ISO 5356-1, ISO 5356-2 and ISO 5367.

201.102.5.5 ANAESTHETIC BREATHING SYSTEM component port connector

If an ANAESTHETIC BREATHING SYSTEM component port connector is OPERATOR-detachable without the use of a TOOL, it shall be a 22 mm male conical connector with coaxial 15 mm female conical connector complying with ISO 5356-1 or a proprietary fitting incompatible with connectors complying with ISO 5356-1 and BREATHING TUBES complying with ISO 5367.

Check compliance by functional testing and application of the tests of ISO 5356-1 and ISO 5367.

201.102.5.6 * Inspiratory and expiratory port connectors of a CIRCLE ABSORBER ASSEMBLY

If the connections to inspiratory or expiratory ports of a CIRCLE ABSORBER ASSEMBLY are OPERATOR-detachable without the use of a TOOL, the ports shall be a 22 mm male conical connector with or without coaxial 15 mm female conical connector complying with ISO 5356-1 or ISO 5356-2. The axis of these ports shall be within ±50° of the horizontal plane.

Check compliance by inspection and application of the tests of ISO 5356-1 and ISO 5356-2.

201.102.5.7 Other port connectors

Port connectors used for other specific purposes (e.g. pressure measurement, gas sample return) shall not be compatible with ISO 5356-1, ISO 5356-2 or ISO 594-2. The port connectors shall be provided with a means of securing closure when not in use. The means of closure shall be non-detachable from the component.

NOTE 1 Attention is drawn to the series ISO 80369 on *small bore connectors for liquids and gases in healthcare applications* which is currently in preparation by ISO/TC 210/IEC SC 62D/JWG 4.

A gas sample return port shall be marked with the words “gas return” or symbol ISO 7000-0795.

A gas sample port shall be marked with the words “gas sample” or symbol ISO 7000-0794.

NOTE 2 Other particular standards, e.g. ISO 8185 for humidifiers, that may be added to an ANAESTHETIC BREATHING SYSTEM also contain requirements for specific ports, e.g. temperature probe.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE.

201.102.6 * Leakage

The leakage from an ANAESTHETIC BREATHING SYSTEM shall not exceed 150 ml/min (15,2 kPa · l/min) at 30 hPa (30 cmH_2O) internal pressure.

Check compliance by functional testing.

201.102.7 * Inspiratory and expiratory pressure/flow rate characteristics

The pressure, either positive or subatmospheric, generated at the PATIENT CONNECTION PORT shall not exceed 6 hPa (6 cmH_2O) at the peak flow rate of 60 l/min at a FRESH GAS flow rate of 10 l/min (±1 l/min) or the maximum FRESH-GAS INLET flow rate specified in the instructions for use, whichever is greater.

The instructions for use shall disclose the inspiratory and expiratory pressure/flow rate characteristics of the ANAESTHETIC BREATHING SYSTEM, including the pressure at 60 l/min.

Check compliance by functional testing under the worst case scenario and inspection of the instructions for use.

201.102.8 ANAESTHETIC BREATHING SYSTEM components

201.102.8.1 * Y-PIECE

The connectors of a Y-PIECE, not permanently attached to a BREATHING TUBE, shall be either 22 mm male conical connectors, with a recess, complying with ISO 5356-1 or other connectors compatible with a BREATHING TUBE complying with ISO 5367.

Check compliance by inspection and application of the tests of ISO 5356-1 or ISO 5367, as applicable.

201.102.8.2 * EXHAUST VALVE

An EXHAUST VALVE shall not be placed between the inspiratory valve and the Y-PIECE.

An OPERATOR-adjustable EXHAUST VALVE with a rotary control shall progressively increase the opening pressure with movement of the control in a clockwise direction. Movement of the control to a fully clockwise position need not close the EXHAUST VALVE completely.

For an EXHAUST VALVE not integrated into the ANAESTHETIC BREATHING SYSTEM, the instructions for use shall disclose:

— the opening pressure;

— the pressure/flow-rate characteristics;

— the pressure drop with any EXHAUST VALVE control fully open at a flow rate of 30 l/min;

— for an EXHAUST VALVE that can be fully closed, the leakage to atmosphere in the fully closed position at a pressure of 30 hPa (30 cmH_2O).

Check compliance by inspection, functional testing and inspection of the instructions for use.

201.102.9 CIRCLE ABSORBER ASSEMBLIES

201.102.9.1 * Constructional requirements

A CIRCLE ABSORBER ASSEMBLY not integrated into the ANAESTHETIC BREATHING SYSTEM shall incorporate inspiratory and expiratory valves or other means of ensuring unidirectional gas flow. If these valves or means can be detached from the CIRCLE ABSORBER ASSEMBLY, the method of attachment shall be by means of connectors which are non-interchangeable with each other and which are not compatible with any of the connectors specified in ISO 5356-1 and ISO 5356-2.

The carbon dioxide absorbent container and its position on the ANAESTHETIC WORKSTATION shall permit the colour change of the absorbent to be visible from the OPERATOR'S intended position. A CIRCLE ABSORBER ASSEMBLY may include means to permit changing the absorbent without opening the gas pathway to the atmosphere.

Check compliance by inspection, functional testing and application of the tests of ISO 5356-1 and ISO 5356-2.

201.102.9.2 * Absorbent bypass mechanism

Unless the absorbent bypass mechanism is intended to function at one or more intermediate settings, its control shall have only “on” and “off” positions. The position marked “off” shall mean that the gas does not pass through the absorbent. The instructions for use shall disclose the proportion of gas that does not pass through the absorbent with the bypass control at intermediate settings, if so equipped, and at the “on” setting.

The requirements for leakage (201.102.6) and resistance to flow rate (201.102.9.3) shall be met in the “on” and “off” positions and, if provided, any intermediate position of the bypass mechanism.

Indication of the absorbent bypass mechanism setting shall be CLEARLY LEGIBLE from the intended OPERATOR'S position.

A CIRCLE ABSORBER ASSEMBLY with an OPERATOR-controlled absorbent bypass mechanism shall permit changing the absorbent without opening the gas pathway to the atmosphere when the control is in the “off” position.

Check compliance by inspection, functional testing and the tests of IEC 60601-1:2005, 7.1.

201.102.9.3 Resistance to flow rate

A CIRCLE ABSORBER ASSEMBLY not integrated into an ANAESTHETIC BREATHING SYSTEM, when assembled with other components according to the instructions for use to form a complete ANAESTHETIC BREATHING SYSTEM, shall meet the resistance to flow rate requirements of 201.102.7.

The instructions for use shall describe the inspiratory and expiratory pressure/flow rate characteristics of the CIRCLE ABSORBER ASSEMBLY, including the pressure at 60 l/min.

Check compliance by the tests of 201.102.7 with the CIRCLE ABSORBER ASSEMBLY connected to each ANAESTHETIC BREATHING SYSTEM indicated in the instructions for use.

201.102.10 INSPIRATORY and EXPIRATORY VALVES

201.102.10.1 * Constructional requirements

Unless a means of indicating a malfunction is provided, inspiratory and expiratory valves shall be designed and located such that their action is visible to the OPERATOR. Inspiratory valves and expiratory valves shall not be located in the Y-PIECE. The instructions for use shall disclose information as to how the OPERATOR can check the function of these valves.

Check compliance by inspection and functional testing as disclosed in the instructions for use.

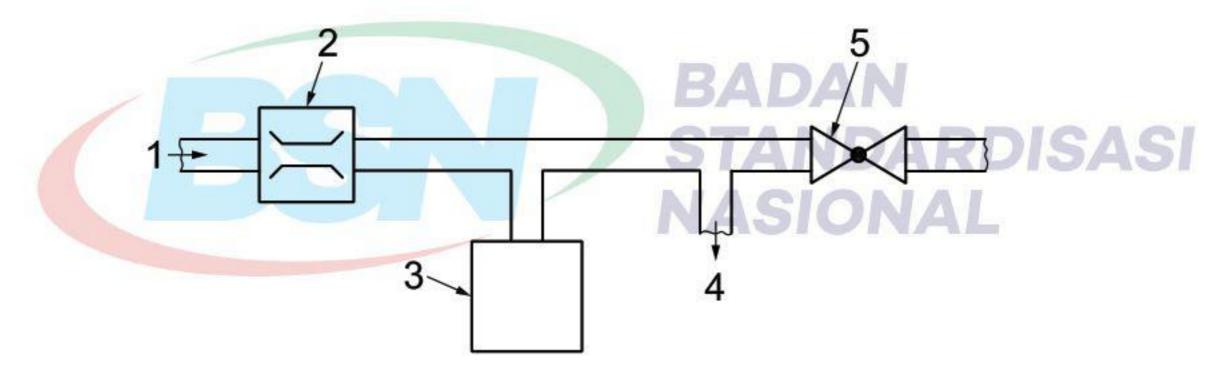
201.102.10.2 Opening pressure

At a flow rate of 20 ml/min the pressure to open a dry valve shall not exceed 1,2 hPa (1,2 cmH_2O).

Check compliance with the following test or an equivalent:

Utilize a flow rate measuring device capable of indicating a flow rate of 60 ml/min, and a pressure measuring device, accurate to within ±0,1 hPa (±0,1 cmH_2O) at a pressure of 15 hPa (15 cmH_2O).

Connect a pressure source on the upstream side of the valve and connect the pressure measuring device to record the pressure generated at the input side of the valve, as shown in Figure 201.104.

Allow the valve to close and determine the opening pressure by adjusting the flow rate of gas to 20 ml/min and recording the peak pressure attained on the upstream side of the valve.

Key

1 from pressure source

2 flow rate measuring device

3 rigid container

4 to pressure measuring device

5 inspiratory or expiratory unidirectional valve

Figure 201.104 — Arrangement of components for test of opening pressure of UNIDIRECTIONAL VALVES

201.102.10.3 Pressure flow-rate characteristics

For inspiratory and expiratory UNIDIRECTIONAL VALVES that are not integrated in the ANAESTHETIC BREATHING SYSTEM, the instructions for use shall disclose the pressure/flow-rate characteristics of the valves under both wet and dry conditions, including the pressure drop at a flow rate of 60 l/min.

Check compliance by inspection of the instructions for use and the following test or an equivalent:

Utilize a flow-rate-measuring device capable of indicating a flow rate of 5 l/min, 30 l/min and 60 l/min, and a pressure-measuring device, accurate to within ±0,1 hPa (±0,1 cmH_2O) at a pressure of 1,5 hPa (1,5 cmH_2O).

Connect the pressure source on the input side of the valve, connect the pressure-measuring device to record the pressure generated at the input side of the valve, and connect the flow-rate-measuring device between the pressure source and the pressure-measuring device. Adjust the flow rate to 5 l/min, 30 l/min, and 60 l/min respectively. Record the pressure generated.

201.102.10.4 * Reverse flow rate and dislocation

The reverse flow rate through the valve shall not exceed 60 ml/min at a pressure up to 5,0 hPa (5,0 cmH_2O). The valve disc or flap shall not become dislocated on application of a reverse pressure of 50 hPa (50 cmH_2O) and following the application of this pressure, the reverse flow rate through the UNIDIRECTIONAL VALVES shall not exceed 60 ml/min at a pressure up to 5,0 hPa (5,0 cmH_2O).

NOTE Typically the most significant reverse flow rate with disc-type valves is at pressures of less than 0,5 hPa (0,5 cmH_2O), whereas with flap valves it can be at a higher pressure.

Check compliance by functional testing.

201.102.11 * FRESH-GAS INLET

An OPERATOR-accessible FRESH-GAS INLET should have a means to prevent unintentional disconnection of the ANAESTHETIC BREATHING SYSTEM.

In a CIRCLE ABSORBER ASSEMBLY, it is recommended that the FRESH-GAS INLET be placed between the absorbent container and the inspiratory valve.

201.103 Additional requirements for an ANAESTHETIC GAS SCAVENGING SYSTEM

201.103.1 Identification, marking and documents

201.103.1.1 Marking

The RECEIVING SYSTEM of an ANAESTHETIC GAS SCAVENGING SYSTEM, if physically discrete, shall have CLEARLY LEGIBLE marking that indicates its suitability for use with a high-flow-rate or low-flow-rate DISPOSAL SYSTEM.

EXAMPLE 1 >75 l/min, high-flow-rate or <50 l/min, low-flow-rate.

If colour coding is used to identify components as being specific for use with an ANAESTHETIC GAS SCAVENGING SYSTEM, it shall be magenta.

EXAMPLE 2 10P hue/4/10 specified in the Munsell Book of Color[22].

Check compliance by inspection.

201.103.1.2 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the ANAESTHETIC GAS SCAVENGING SYSTEM complies with this International Standard;

b) the rated maximum flow rate and minimum exhaust flow rate of the DISPOSAL SYSTEM with which the TRANSFER SYSTEM and RECEIVING SYSTEM are intended to be used.

Check compliance by inspection of the instructions for use.

201.103.2 Pressure relief PROTECTION DEVICE

The pressure relief PROTECTION DEVICE, if provided, shall be accessible for cleaning and/or servicing.

NOTE When the pressure relief PROTECTION DEVICE is actuated, gases can be spilled into the atmosphere.

Check compliance by inspection.

201.103.3 Basic requirements

201.103.3.1 NORMAL CONDITION

201.103.3.1.1 ANAESTHETIC GAS SCAVENGING SYSTEM inlet pressure

The pressure at the inlet to the ANAESTHETIC GAS SCAVENGING SYSTEM shall not exceed 350 Pa (3,5 cmH_2O):

— with a flow of air of 75 l/min into the inlet of the ANAESTHETIC GAS SCAVENGING SYSTEM;

— with the RATED MINIMUM EXHAUST FLOW RATE and the RATED MAXIMUM EXHAUST FLOW RATE as indicated in the instructions for use.

Check compliance by inspection of the instructions for use and functional testing.

201.103.3.1.2 INDUCED FLOW RATE

The INDUCED FLOW RATE at the inlet to the ANAESTHETIC GAS SCAVENGING SYSTEM shall not exceed 50 ml/min at the RATED MAXIMUM EXHAUST FLOW RATE indicated in the instructions for use of the TRANSFER and RECEIVING SYSTEM.

Check compliance by inspection of the instructions for use and functional testing.

201.103.3.1.3 Flow resistance

The pressure drop across a LOW-FLOW TRANSFER AND RECEIVING SYSTEM shall be

— not less than 10 hPa (10 cmH_2O) at 50 l/min,

— not greater than 20 hPa (20 cmH_2O) at 25 l/min.

The pressure drop across a HIGH-FLOW TRANSFER AND RECEIVING SYSTEM shall be

— not less than 10 hPa (10 cmH_2O) at 80 l/min,

— not greater than 20 hPa (20 cmH_2O) at 50 l/min.

Check compliance by functional testing.

201.103.3.1.4 SPILLAGE to atmosphere

SPILLAGE to atmosphere shall not exceed 100 ml/min under the following conditions:

a) a breathing pattern in the ANAESTHETIC BREATHING SYSTEM or ANAESTHETIC VENTILATOR of

  — frequency of 20 cycles/min,

  — *I/E* ratio 1:1,

  — tidal volume of 1 l;

b) at the RATED MINIMUM EXHAUST FLOW RATE indicated in the instructions for use;

c) at EXHAUST FLOW RATES between 25 l/min and 50 l/min for a LOW-FLOW TRANSFER AND RECEIVING SYSTEM;

d) at EXHAUST FLOW RATES between 50 l/min and 80 l/min for a HIGH-FLOW TRANSFER AND RECEIVING SYSTEM.

Check compliance by inspection of the instructions for use and functional testing.

201.103.3.1.5 Leakage

The leakage of gas from the TRANSFER and RECEIVING SYSTEM shall be less than 100 ml/min at a gas flow rate of 10 ± 0,5 l/min. The technical description shall describe how to measure the leakage of the TRANSFER and RECEIVING SYSTEM.

NOTE Leakage can be greater under SINGLE FAULT CONDITION.

Check compliance by inspection of the technical description and testing according to the technical description.

201.103.3.2 SINGLE FAULT CONDITION

201.103.3.2.1 Pressure

Under SINGLE FAULT CONDITIONS, the pressure at the inlet to the ANAESTHETIC GAS SCAVENGING SYSTEM shall not exceed 20 hPa (20 cmH_2O) with an EXHAUST FLOW RATE of 75 l/min.

Check compliance by functional testing.

201.103.3.2.2 INDUCED FLOW RATE

Under SINGLE FAULT CONDITIONS, the induced flow rate at the inlet to the ANAESTHETIC GAS SCAVENGING SYSTEM shall not exceed 500 ml/min at the RATED MAXIMUM EXHAUST FLOW RATE indicated in the instructions for use of the TRANSFER SYSTEM and RECEIVING SYSTEM.

Check compliance by inspection of the instructions for use and functional testing.

201.103.3.2.3 Subatmospheric pressure at the input of the RECEIVING SYSTEM

Under SINGLE FAULT CONDITIONS, the pressure at the input of the RECEIVING SYSTEM shall not be more than 50 Pa (0,5 cmH_2O) below ambient pressure at the RATED MAXIMUM EXHAUST FLOW RATE indicated in the instructions for use of the TRANSFER and RECEIVING SYSTEM.

Check compliance by inspection of the instructions for use and functional testing.

201.103.4 Connectors

201.103.4.1 Hose connectors

Connectors fitted to hoses shall be permanently attached, i.e. not OPERATOR-detachable without the use of a TOOL.

Check compliance by inspection.

201.103.4.2 Connections between parts of TRANSFER SYSTEMS and RECEIVING SYSTEMS

Connectors between subassemblies of TRANSFER SYSTEMS and RECEIVING SYSTEMS:

a) shall be either:

— 30 mm conical connectors complying with ISO 5356-1; or

— designed to prevent mis-assembly;

b) shall not be compatible with:

— TERMINAL UNITS as specified in ISO 9170-1 and ISO 9170-2;

— LOW-PRESSURE HOSE ASSEMBLIES as specified in ISO 5359;

— conical connectors complying with ISO 5356-1 or ISO 5356-2, other than size 30 mm.

Check compliance by inspection and by application of the tests of ISO 5356-1, ISO 5356-2, ISO 5359, ISO 9170-1 and ISO 9170-2.

201.103.4.3 Connections to diverting respiratory gas monitors

If provided, connectors on the ANAESTHETIC GAS SCAVENGING SYSTEM intended for the scavenging of sample gas from a diverting respiratory gas monitor shall not be compatible with ISO 594-2.

NOTE Attention is drawn to the series ISO 80369 on *small bore connectors for liquids and gases in healthcare applications* which is currently in preparation by ISO/TC 210/IEC SC 62D/JWG 4.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE.

201.103.5 TRANSFER SYSTEM

201.103.5.1 Inlet

If an inlet connector of a TRANSFER SYSTEM is OPERATOR-detachable without the use of a TOOL, it shall be either

a) a 30 mm diameter female conical connector complying with ISO 5356-1 and the TRANSFER SYSTEM shall include a means of pressure relief at the inlet, or

b) a proprietary connector that complies with 201.103.4.2 b).

Check compliance by inspection and by application of the tests of ISO 5356-1, ISO 5356-2, ISO 5359, ISO 9170-1 and ISO 9170-2, as applicable.

201.103.5.2 Outlet

If an outlet connector of a TRANSFER SYSTEM is OPERATOR-detachable without the use of a TOOL, it shall be either

a) a 30 mm diameter male conical connector complying with ISO 5356-1, or

b) a proprietary connector that complies with 201.103.4.2 b).

Check compliance by inspection and by application of the tests of ISO 5356-1, ISO 5356-2, ISO 5359, ISO 9170-1 and ISO 9170-2, as applicable.

201.103.6 RECEIVING SYSTEM

201.103.6.1 Inlet connectors

If an inlet connector of a RECEIVING SYSTEM is OPERATOR-detachable without the use of a TOOL, it shall be either

a) a 30 mm diameter female conical connector complying with ISO 5356-1, or

b) a proprietary connector that complies with 201.103.4.2 b).

Check compliance by inspection and by application of the tests of ISO 5356-1, ISO 5356-2, ISO 5359, ISO 9170-1 and ISO 9170-2, as applicable.

201.103.6.2 * Outlet connectors

If the outlet connector is OPERATOR-detachable without the use of a TOOL, it shall be either

a) a connector 1L complying with ISO 9170-2, for a LOW-FLOW TRANSFER AND RECEIVING SYSTEM, or

b) a connector 1H complying with ISO 9170-2, for a HIGH-FLOW TRANSFER AND RECEIVING SYSTEM.

NOTE In some countries, alternative designs with equivalent levels of RISK CONTROL are required.

Check compliance by inspection and by application of the tests of ISO 9170-2.

201.103.6.3 Hoses

If hoses are used in the RECEIVING SYSTEM to connect to the DISPOSAL SYSTEM, they shall comply with the following requirements for vacuum services:

— resistance to kinking, as specified in ISO 5359:2008, 4.4.6;

— resistance to occlusion, as specified in ISO 5359:2008, 5.7.

Check compliance by inspection and by application of the tests of ISO 5359:2008 using the conditions specified in ISO 5359:2008, 5.1.

201.103.6.4 Particle filter

If provided, a particle filter shall be located on the DISPOSAL SYSTEM side of the RECEIVING SYSTEM. It shall be OPERATOR-detachable without the use of a TOOL.

Check compliance by inspection.

201.103.7 TRANSFER SYSTEMS AND RECEIVING SYSTEMS with integral POWER DEVICE

If the POWER DEVICE is an integral part of the TRANSFER SYSTEM or RECEIVING SYSTEM, the POWER DEVICE shall comply with the applicable requirements of ISO 7396-2 and the outlet of the RECEIVING SYSTEM or the DISPOSAL HOSE shall be a Type 2 connector as specified in ISO 9170-2.

Check compliance by application of the tests of ISO 7396-2 and ISO 9170-2.

201.103.8 Visual indicator

The ANAESTHETIC GAS SCAVENGING SYSTEM shall visually indicate when the EXHAUST FLOW RATE is within the appropriate range for the TRANSFER and RECEIVING SYSTEM.

EXAMPLE Quantitative information such as flow rates or pressure values or qualitative devices such as reservoir bags filling and discharging or go/no-go indicators.

Check compliance by inspection.

201.104 Additional requirements for an ANAESTHETIC VAPOUR DELIVERY SYSTEM

201.104.1 Identification, marking and documents

201.104.1.1 * Marking

The ANAESTHETIC VAPOUR DELIVERY SYSTEM shall be marked with the safety sign for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005+TC1, Table D.2, number 10). Such marking shall be CLEARLY LEGIBLE from the intended OPERATOR’S position.

The control activating the delivery of a specific vapour of a volatile anaesthetic agent shall be marked with the generic name in full spelling or in abbreviated form as given in the following list:

— Desflurane – “DES”

— Enflurane – “ENF”

— Halothane – “HAL”

— Isoflurane – “ISO”

— Sevoflurane – “SEV”

If colour coding is used, it shall be in accordance with ISO 5360.

Either the maximum and minimum filling levels shall be marked on the liquid level indicator, or the actual usable volume shall be displayed.

Check compliance by inspection.

201.104.1.2 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM complies with this International Standard;

b) a statement to the effect that an ANAESTHETIC WORKSTATION used with this ANAESTHETIC VAPOUR DELIVERY SYSTEM needs to comply with this International Standard;

c) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM is to be used with halogenated anaesthetic agent MONITORING EQUIPMENT complying with ISO/IEC 80601-2-55;

d) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM is to be used with an ANAESTHETIC GAS DELIVERY SYSTEM complying with this International Standard;

e) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM is to be used with an ANAESTHETIC GAS SCAVENGING SYSTEM complying with this International Standard;

f) the performance of the ANAESTHETIC VAPOUR DELIVERY SYSTEM including the effects of variation in ambient temperature, ambient pressure, resistance, tilting, back pressure, subatmospheric pressure, input flow rate and gas composition over the range of operating conditions specified in the instructions for use;

g) the carrier gas, gas flow rate(s) and analytical technique(s) recommended for measuring the output of the ANAESTHETIC VAPOUR DELIVERY SYSTEM;

h) a statement to the effect that the vaporizer should not be used between zero and the first calibration, if applicable;

i) the volume at the maximum and minimum fill levels and the total capacity.

Check compliance by inspection of the instructions for use.

201.104.2 Delivered vapour concentration

201.104.2.1 Controls

The control of an ANAESTHETIC VAPOUR DELIVERY SYSTEM shall be vapour concentration calibrated for each intended ANAESTHETIC GAS. The set concentration as well as the units of measurement shall be marked on the ANAESTHETIC VAPOUR DELIVERY SYSTEM or its display for the calibrated range. It shall not be possible to set the control above the calibrated range. The controls shall be marked with “0” or “Off”, or with both, if the “0” position is not also the “Off” position, or with “Standby” if “Off” is not provided. If a rotary control is provided, the ANAESTHETIC GAS concentration shall increase when the control is turned anticlockwise. Means to prevent the unintentional operation of the ANAESTHETIC VAPOUR DELIVERY SYSTEM control shall be provided.

NOTE 1 Attention is drawn to the fact that the requirement in this subclause is contrary to the convention for direction of rotation for electronic controls.

NOTE 2 When the ANAESTHETIC VAPOUR DELIVERY SYSTEM is marked with "Off" or "Standby" this indicates that no anaesthetic vapour is intentionally being added to the output flow. "Standby" on an electrically operated ANAESTHETIC VAPOUR DELIVERY SYSTEM indicates that the ANAESTHETIC VAPOUR DELIVERY SYSTEM is enabled. "0" indicates that no more than the prescribed tolerance as indicated in the instructions for use is being added to the output flow.

If the ANAESTHETIC VAPOUR DELIVERY SYSTEM should not be used between "Off" and the first graduation above zero, this shall be disclosed in the instructions for use.

Check compliance by inspection, functional testing and, if applicable, by inspection of the instructions for use.

201.104.2.2 * Accuracy

When the ANAESTHETIC VAPOUR DELIVERY SYSTEM is tested with the carrier gas and the analytical technique recommended in the instructions for use [see 201.104.1.2 g)]:

— the delivered concentration at all graduations other than "Off", "standby", or the "0" position if this is also the "Off" position, from the ANAESTHETIC VAPOUR DELIVERY SYSTEM shall not deviate by more than +30 % or −20 % from the concentration setting or by more than +7,5 % or −5 % of the maximum setting, whichever is greater;

— the delivered concentration when the ANAESTHETIC VAPOUR DELIVERY SYSTEM control is in the "Off" position, the "standby" position or the "0" position if this is also the "Off" position, shall not exceed 0,1 % volume fraction.

Check for compliance by visual inspection, functional testing and with the following test.

a) *Test the ANAESTHETIC VAPOUR DELIVERY SYSTEM on a calibrated test rig capable of supplying the necessary gas flow rates and pressures required by the test conditions, or on an ANAESTHETIC WORKSTATION, with the ANAESTHETIC VENTILATOR and ANAESTHETIC BREATHING SYSTEM recommended in the instructions for use.*

b) *Connect an anaesthetic vapour analyser to the FRESH-GAS OUTLET of the ANAESTHETIC WORKSTATION or to the inlet of the ANAESTHETIC BREATHING SYSTEM if there is no FRESH-GAS OUTLET or if applicable, to the inspiratory port of the ANAESTHETIC VENTILATOR. Ensure that the components downstream of the ANAESTHETIC VAPOUR DELIVERY SYSTEM do not affect the test results, for example, by absorbing the volatile anaesthetic agents, by imposing time delays on response, or by leakage.*

c) *Place the calibrated test rig or the ANAESTHETIC WORKSTATION, as applicable, with the specified test equipment and volatile anaesthetic agent in the test room for at least 3 h at (20 ± 3) °C and maintain this temperature throughout the test.*

d) *Fill the ANAESTHETIC VAPOUR DELIVERY SYSTEM with the appropriate liquid anaesthetic agent to approximately half of the maximum usable volume, and leave it to stand for at least 45 min.*

e) *If the instructions for use recommend that when power is applied to the ANAESTHETIC VAPOUR DELIVERY SYSTEM , a warm-up period be allowed before use, apply power for at least that period before continuing. This period may be within the 45 min mentioned in d).*

f) *With the ANAESTHETIC VAPOUR DELIVERY SYSTEM control in the "Off", "0" or, if applicable, the "Standby" position, set the gas flow rate through the ANAESTHETIC WORKSTATION to (2 ± 0,2) l/min and adjust the ANAESTHETIC VENTILATOR to give (15 ± 2) breaths/min at an I/E ratio of 1:2 ± 20 % with the inspiratory flow rate control set to maximum. For an ANAESTHETIC WORKSTATION in which the FRESH GAS flow rate is determined by the ANAESTHETIC VENTILATOR settings, set the ANAESTHETIC VENTILATOR to give a minute volume of (2 ± 0,2) l.*

g) *Introduce a maximum pressure fluctuation of (20 ± 3) hPa [(20 ± 3) cmH_2O], above ambient, at the FRESH-GAS OUTLET ensuring that the decay time during the expiration period (from 100 % of the FRESH-GAS OUTLET pressure at the end of the inspiration period to 33 % of this pressure) is less than 0,6 s.*

NOTE This can be achieved by using a test lung having a compliance of 0,2 l/kPa and an appropriate resistance.

h) *Maintain the pressure fluctuations for 3 min and after that time measure the concentration of anaesthetic vapour delivered over a further 1 min period while maintaining the pressure fluctuation. Calculate the average vapour concentration in the total delivered gas flow.*

i) *Repeat f) to h) with the* ANAESTHETIC VAPOUR DELIVERY SYSTEM *set to each of the other settings and in the order given in Table 201.104. If the* ANAESTHETIC VAPOUR DELIVERY SYSTEM *is not marked with the concentration settings given in Table 201.104, use the nearest settings on the* ANAESTHETIC VAPOUR DELIVERY SYSTEM*. If any setting given in Table 201.104 is equidistant between settings on the* ANAESTHETIC VAPOUR DELIVERY SYSTEM*, use the lower setting on the* ANAESTHETIC VAPOUR DELIVERY SYSTEM*.*

Table 201.104 — Settings to be used for testing delivered concentration

Order of test	Setting (% V/V of anaesthetic vapour)
1	off, standby, and zero, if separately marked
2[a]	lowest graduation above zero
3	10 % FS
4	20 % FS
5	50 % FS
6	75 % FS
7	maximum graduation (full scale)

[a] If 10 % of full scale (FS) is the lowest graduation, step 2 is omitted.

j) *Repeat f) to i) using a* FRESH GAS *flow rate of (8 ± 0,8) l/min and a pressure fluctuation at the* FRESH-GAS OUTLET *of (50 ± 4) hPa [(50 ± 4) cmH$_2$O]. For an* ANAESTHETIC WORKSTATION *in which the* FRESH GAS *flow rate is determined by the* ANAESTHETIC VENTILATOR *settings, set these to give a minute volume of (8 ± 0,8) l.*

201.104.3 * Vapour output during and after oxygen flush

During and after oxygen flush, the anaesthetic vapour output of the ANAESTHETIC VAPOUR DELIVERY SYSTEM shall not increase by more than 20 %.

Check compliance with the following test:

a) *Repeat 201.104.2.2 j) by measuring the output of anaesthetic vapour (concentration of vapour x volume of gas) for 1 min before, during a 10 s activation of the oxygen flush, and for 30 s after the oxygen flush activation, instead of introducing a pressure fluctuation at the* FRESH-GAS OUTLET*. Compare these three measurements expressed as volume of vapour per unit of time.*

NOTE The volume of gas can be determined, for example, by the integrating flow rate or by collecting the gas during the specified period.

b) *Repeat a) using a steady subatmospheric pressure of 100 hPa (100 cmH$_2$O). Compare these three measurements expressed as volume of vapour per unit of time.*

201.104.4 Connectors

If a conical connector that is OPERATOR-detachable without the use of a TOOL is used at the inlet or outlet of an ANAESTHETIC VAPOUR DELIVERY SYSTEM, it shall be 23 mm in size complying with ISO 5356-1. The connector at the inlet shall be male and that at the outlet shall be female. Any other means of connection for an ANAESTHETIC VAPOUR DELIVERY SYSTEM shall ensure that the ANAESTHETIC VAPOUR DELIVERY SYSTEM can only be fitted so that the gas flow through it is in the intended direction.

Check compliance by visual inspection and by application of the tests of ISO 5356-1.

201.104.5 Cross-contamination

For an ANAESTHETIC WORKSTATION capable of delivering more than one vapour of a volatile anaesthetic agent, means shall be provided to prevent the simultaneous delivery of more than one vapour of a volatile anaesthetic agent to the FRESH GAS and to prevent cross-contamination of the content of one ANAESTHETIC VAPOUR DELIVERY SYSTEM with a vapour of another volatile anaesthetic agent.

See also 201.101.3.

Check compliance by inspection and functional testing.

201.104.6 ANAESTHETIC VAPOUR DELIVERY SYSTEM filling

The filling port shall be marked with the generic name of the anaesthetic agent in full spelling or in abbreviated form as specified in 201.104.1.1.

Means to prevent filling the ANAESTHETIC VAPOUR DELIVERY SYSTEM with the incorrect liquid anaesthetic agent shall be provided. If a rectangular agent-specific keyed filling system is used, it shall comply with ISO 5360.

The volume of liquid anaesthetic agent required to fill the reservoir of the ANAESTHETIC VAPOUR DELIVERY SYSTEM to the maximum filling level, and the total capacity shall be disclosed in the instructions for use. The anaesthetic agent bottle may be used as the anaesthetic agent reservoir.

In NORMAL USE, it shall not be possible to overfill the ANAESTHETIC VAPOUR DELIVERY SYSTEM such that

a) its performance is affected, or

b) the fluid level is no longer evident.

Check compliance by inspection, functional testing and application of the tests of ISO 5360.

201.104.7 ANAESTHETIC VAPOUR DELIVERY SYSTEM component packaging

ANAESTHETIC VAPOUR DELIVERY SYSTEM components shall be packaged in such a way as to reduce the RISK of the incomplete removal of the packaging before use to acceptable levels.

NOTE This is to prevent accidental retention of the packaging, e.g. transparent wrapper, caps, lids, covers, and to ensure its removal by the OPERATOR prior to use.

Check compliance by inspection.

201.105 Additional requirements for an ANAESTHETIC VENTILATOR

201.105.1 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the ANAESTHETIC VENTILATOR complies with this International Standard;

b) a statement to the effect that the ANAESTHETIC VENTILATOR is intended to be used with an ANAESTHETIC BREATHING SYSTEM that complies with this International Standard;

c) unless the ANAESTHETIC VENTILATOR is an integral part of the ANAESTHETIC WORKSTATION, information on how to connect to an ANAESTHETIC WORKSTATION and ANAESTHETIC BREATHING SYSTEM;

d) the operational characteristics of the ANAESTHETIC VENTILATOR including, where applicable, the following:

   1) range of DELIVERED VOLUMES (tidal and minute);

   2) range of cycling frequency,

3) range of I/E ratios,

4) range of values that can be set as the maximum pressure at the PATIENT CONNECTION PORT during NORMAL USE in the inspiratory phase and the means by which that maximum pressure is ensured (e.g. pressure cycling, pressure limitation),

5) inspiratory flow rate and pressure characteristics,

6) modes of cycling,

7) the minimum pressure at the PATIENT CONNECTION PORT (during NORMAL USE and under SINGLE FAULT CONDITION),

NOTE This minimum pressure can be subatmospheric.

8) PEEP range,

9) if there is a facility for subatmospheric pressure in the expiratory phase, the limiting pressure and generated pressure,

10) characteristics of the means used for initiation of the inspiratory phase, e.g. PATIENT trigger,

11) interdependence of controls,

12) if applicable, a statement that the ANAESTHETIC VENTILATOR compensates for ANAESTHETIC BREATHING SYSTEM compliance and a description of the method of compliance compensation;

e) any restrictions on the location and/or sequence of components within the ANAESTHETIC BREATHING SYSTEM as they relate to the ANAESTHETIC VENTILATOR;

EXAMPLE Where such components are flow-direction-sensitive.

f) the range of internal volume of any ANAESTHETIC BREATHING SYSTEM ACCESSORIES or other components or subassemblies recommended by the MANUFACTURER;

g) for an ANAESTHETIC VENTILATOR supplied separately, a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with an AIRWAY PRESSURE MONITORING EQUIPMENT complying with this International Standard (see 201.12.4.109) before being put into service and a description on how to connect that item.

Check compliance by inspection of the instructions for use.

201.105.2 Pressure limitation PROTECTION DEVICE

NOTE The ANAESTHETIC WORKSTATION is expected to have one MAXIMUM LIMITED PRESSURE PROTECTION DEVICE and one adjustable pressure limitation PROTECTION DEVICE which can be located either in the ANAESTHETIC BREATHING SYSTEM or in the ANAESTHETIC VENTILATOR (see 201.102.2.1, 201.102.2.2, 201.105.2.1 and 201.105.2.2).

201.105.2.1 MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

The ANAESTHETIC VENTILATOR shall be equipped with a protection device to limit the pressure at the PATIENT CONNECTION PORT to less than 125 hPa (125 cmH_2O) in NORMAL CONDITION and SINGLE FAULT CONDITION.

Check compliance by functional testing.

201.105.2.2 * ADJUSTABLE PRESSURE LIMITATION PROTECTION DEVICE

The ANAESTHETIC VENTILATOR shall be equipped with a PROTECTION DEVICE to limit the pressure at the PATIENT CONNECTION PORT to an OPERATOR-adjustable pressure. If not so equipped, the instructions for use of the ANAESTHETIC VENTILATOR shall contain a statement to the effect that the ANAESTHETIC BREATHING SYSTEM is to

be provided with a PROTECTION DEVICE to limit the pressure at the PATIENT CONNECTION PORT to an OPERATOR-adjustable pressure complying with this International Standard before the ANAESTHETIC WORKSTATION is put into service and shall describe how to connect that item to the ANAESTHETIC WORKSTATION available (e.g. in integration instructions) upon request. This PROTECTION DEVICE shall ensure that the pressure at the PATIENT CONNECTION PORT does not exceed the maximum OPERATOR-settable value by more than 15 % or 10 hPa (10 cmH_2O), whichever is greater, in NORMAL CONDITION.

Check compliance by functional testing and, if applicable, by inspection of the instructions for use.

201.105.3 Activation of automatic ventilation

If the ANAESTHETIC VENTILATOR is an integral part of the ANAESTHETIC WORKSTATION, only one control shall be provided to change from automatic ventilation to spontaneous or manually assisted breathing and vice versa.

Check compliance by inspection.

201.105.4 BREATHING SYSTEM connection port

If a conical OPERATOR-accessible port that connects the ANAESTHETIC VENTILATOR to the ANAESTHETIC BREATHING SYSTEM is provided, that port shall be a 22 mm male conical connector complying with ISO 5356-1 or ISO 5356-2.

Check compliance by application of the tests of ISO 5356-1 or ISO 5356-2.

201.105.5 Interruption of the electrical or pneumatic POWER SUPPLY

The ANAESTHETIC VENTILATOR shall be so designed that in the event of an electrical or pneumatic POWER SUPPLY failure, the supply of FRESH GAS to the ANAESTHETIC BREATHING SYSTEM is either unaffected, or an alternative means of FRESH GAS delivery is available.

EXAMPLE An external flow-metering device directly connected to the medical gas supply.

Under POWER SUPPLY failure conditions, it shall be possible to ventilate the PATIENT manually. This may be achieved with an OPERATOR-powered RESUSCITATOR complying with ISO 10651-4.

Under POWER SUPPLY failure conditions, OPERATOR actions necessary to ensure the continued supply of FRESH GAS to or ventilation of the PATIENT shall be disclosed in the instructions for use. VERIFICATION of these capabilities shall be included in the pre-use checklist (see 201.7.9.2.8).

Check compliance by inspection of the instructions for use, inspection and functional testing.

201.105.6 EXHAUST PORT connector

If an EXHAUST PORT connector is OPERATOR-detachable without the use of a TOOL, the EXHAUST PORT connector shall be:

a) marked with the word “exhaust” or “AGS” or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol;

b) one of the following:

   1) for an ANAESTHETIC VENTILATOR intended to connect to an ANAESTHETIC GAS SCAVENGING SYSTEM complying with 201.103, a 30 mm male conical connector complying with ISO 5356-1 with means to prevent connection of the orifice to any ANAESTHETIC BREATHING SYSTEM port or ANAESTHETIC VENTILATOR port or component port, or

   2) a proprietary connector that is incompatible with connectors complying with ISO 5356-1 and BREATHING TUBES complying with ISO 5367.

Check compliance by inspection, functional testing and application of the tests of ISO 5356-1 and ISO 5367.

201.105.7 * Timed ventilatory pause

201.105.7.1 Expiratory pause

An ANAESTHETIC VENTILATOR may be equipped with an OPERATOR-controlled means to pause the ANAESTHETIC VENTILATOR in expiration.

The following applies to an expiratory pause.

a) The duration of the expiratory pause may be OPERATOR-configurable or OPERATOR-adjustable.

b) More than one expiratory pause function may be provided.

c) During the expiratory pause, any apnoea-related ventilatory ALARM CONDITION that would be caused by this expiratory pause shall be automatically AUDIO PAUSED or ALARM PAUSED for the duration of the expiratory pause.

d) In addition to the requirements for ALARM SIGNAL inactivation of 6.8.5 of IEC 60601-1-8:2006, the ANAESTHETIC VENTILATOR shall indicate the presence of the expiratory pause with an INFORMATION SIGNAL or LOW PRIORITY ALARM CONDITION.

e) The maximum duration of an expiratory pause shall not exceed 60 s.

f) A means may be provided to initiate the expiratory pause from a SIGNAL INPUT PART/SIGNAL OUTPUT PART. The ANAESTHETIC VENTILATOR should communicate information related to the expiratory pause via a NETWORK/DATA COUPLING.

EXAMPLE NETWORK/DATA COUPLING as specified in ASTM F2761.

NOTE 1 An expiratory pause can be equivalent to placing the ANAESTHETIC VENTILATOR into manual or spontaneous ventilation and automatically resuming automatic ventilation after a predetermined duration.

NOTE 2 The expiratory pause can be used to synchronize radiographic imaging with a deflated lung.

Check compliance by inspection and functional testing.

201.105.7.2 Inspiratory pause

An ANAESTHETIC VENTILATOR may be equipped with an OPERATOR-controlled means to pause automatic ventilation at end-inspiration.

The following applies to an inspiratory pause function.

a) The duration of the inspiratory pause may be non-adjustable, RESPONSIBLE ORGANIZATION-configurable or OPERATOR-adjustable.

b) The high-pressure ALARM CONDITION of 201.4.109 and the PROTECTION DEVICE of 201.105.2 shall remain active during an inspiratory pause.

c) More than one inspiratory pause function may be provided.

d) During the inspiratory pause, any apnoea or sustained AIRWAY PRESSURE ALARM CONDITION that would be caused by this inspiratory pause should be AUDIO PAUSED or ALARM PAUSED for the duration of the inspiratory pause.

e) In addition to the requirements for ALARM SIGNAL inactivation of 6.8.5 of IEC 60601-1-8:2006, the ANAESTHETIC VENTILATOR shall indicate the presence of the inspiratory pause with an INFORMATION SIGNAL or LOW PRIORITY ALARM CONDITION.

f) The maximum duration of a non-adjustable inspiratory pause shall be 10 s; the maximum allowable duration of a configurable or adjustable inspiratory pause shall be 40 s.

g) A means may be provided to initiate the inspiratory pause from a SIGNAL INPUT PART/SIGNAL OUTPUT PART. The ANAESTHETIC VENTILATOR should communicate information related to the expiratory pause via a NETWORK/DATA COUPLING.

EXAMPLE NETWORK/DATA COUPLING as specified in ASTM F2761.

NOTE The inspiratory pause can be used to synchronize radiographic imaging with lung inflation or for recruitment.

Check compliance by inspection and functional testing.

201.105.8 * Subatmospheric pressure

A HIGH PRIORITY ALARM SIGNAL shall be activated when the AIRWAY PRESSURE falls 10 hPa (10 cmH_2O) below atmospheric pressure for more than 1 s.

Check compliance by functional testing.

The ANAESTHETIC VENTILATOR shall continue to function normally after application of negative pressure.

Check compliance by the following test.

a) *Connect a SUCTION system (9), as shown in Figure 201.105, leaving the PATIENT CONNECTION PORT (4) of the closed-SUCTION CATHETER adaptor (5) open to air and the ANAESTHETIC VENTILATOR disconnected. Utilize a closed-SUCTION CATHETER (6) of minimum inside diameter of 2,95 mm [French (Charriere) equivalent size 14 F].*

b) *Adjust the SUCTION equipment as follows:*

— *Close the flow control valve (7) and adjust the vacuum regulator of the SUCTION equipment to an occluded vacuum of 200 hPa (204 cmH_2O) below ambient atmospheric pressure.*

— *Open and set the flow control valve (7) to give a free air flow (SUCTION flow) of:*

1) *30 l/min, for an ANAESTHETIC VENTILATOR intended to provide a DELIVERED VOLUME, $V_{del} \geq 300$ ml;*

2) *15 l/min, for an ANAESTHETIC VENTILATOR intended to provide a DELIVERED VOLUME, 300 ml $\geq V_{del} \geq$ 50 ml;*

3) *5 l/min, for an ANAESTHETIC VENTILATOR intended to provide a DELIVERED VOLUME, $V_{del} \leq 50$ ml.*

c) *Disable the SUCTION flow without affecting the flow control valve setting.*

d) *Connect the ANAESTHETIC VENTILATOR to an ANAESTHETIC BREATHING SYSTEM complying with this International Standard as shown in Figure 201.101 and as indicated in the instructions for use. Connect the ANAESTHETIC BREATHING SYSTEM to the closed-suction catheter adaptor as shown in Figure 201.105.*

e) *Connect a test lung to the PATIENT CONNECTION PORT of the closed-SUCTION CATHETER adaptor. Utilize a test lung with compliance:*

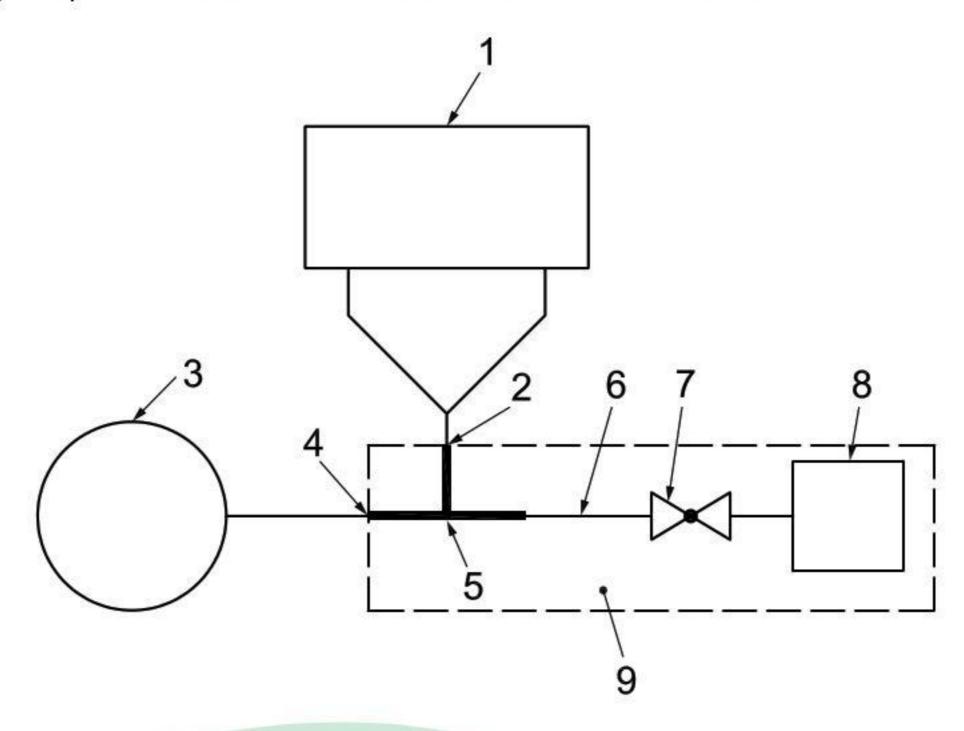
— *10 ml/hPa ± 10 %, for an ANAESTHETIC VENTILATOR intended to provide a DELIVERED VOLUME, $V_{del} \geq 300$ ml;*

— *3 ml/hPa ± 10 %, for an ANAESTHETIC VENTILATOR intended to provide a DELIVERED VOLUME, 300 ml $\geq V_{del} \geq$ 50 ml;*

— *0,5 ml/hPa ± 10 %, for an ANAESTHETIC VENTILATOR intended to provide a DELIVERED VOLUME, $V_{del} \leq 50$ ml.*

f) *Do not enable any special* SUCTION PROCEDURE *mode and retract the closed-*SUCTION CATHETER*.*

g) *Perform any compliance correction as indicated in the instructions for use.*

Key

1 ANAESTHETIC VENTILATOR **under test**

2 PATIENT CONNECTION PORT **of an** ANAESTHETIC BREATHING SYSTEM **before adding the closed-**SUCTION CATHETER **adaptor**

3 **test lung**

4 PATIENT CONNECTION PORT **of an** ANAESTHETIC BREATHING SYSTEM **after adding the closed-**SUCTION CATHETER **adaptor**

5 **closed-**SUCTION CATHETER **adaptor**

6 **2,95 mm (14 F) closed-**SUCTION CATHETER **complying with ISO 8836**

7 **flow control valve (can be incorporated in 8)**

8 SUCTION **equipment complying with ISO 10079-1 or ISO 10079-3**

9 SUCTION **system**

Figure 201.105 — Typical closed-suctioning test setup

h) *Select a volume controlled breath type with the following parameters:*

— *minimum* DELIVERED VOLUME *for the intended* DELIVERED VOLUME *range;*

— *ventilatory frequency of 10 min*$^{-1}$*;*

— *trigger off or, if not so equipped, the most insensitive method and setting.*

i) *Wait until stability is achieved.*

j) *Advance the closed-*SUCTION CATHETER *between 1 cm and 2 cm beyond the* PATIENT CONNECTION PORT *(4).*

k) *Enable the flow control valve (7), without affecting the flow control valve setting, and maintain for 30 s.*

NOTE Some ALARM CONDITIONS might become active and this is an expected possibility.

l) *Terminate the* SUCTION *flow by closing the flow control valve (7) and retract the* SUCTION CATHETER*.*

NOTE Retracting the SUCTION CATHETER into its supplied sleeve can be important to seal the gas pathway and reduce gas leakage.

m) *Wait until stability is achieved.*

n) *Verify that the* ANAESTHETIC VENTILATOR *continues to function as intended.*

EXAMPLE The DELIVERED VOLUME is within specification.

o) *Repeat a) to n) for each intended* DELIVERED VOLUME *range.*

p) *Repeat a) to o) using a pressure-controlled breath type with the following parameters in lieu of h):*

— *ventilation pressure of 5 hPa (5 cmH_2O) or if the* ANAESTHETIC VENTILATOR *cannot be set that low, the lowest setting;*

— *ventilatory frequency of 10 min^{-1};*

— *trigger off or, if not so equipped, the most insensitive setting.*

q) *Repeat a) to o) using the recommended ventilation mode and settings for use with a closed-*SUCTION CATHETER *in lieu of h) unless the recommended ventilation mode and settings have already been tested.*

201.106 Display loops

201.106.1 Pressure-volume loops

If an ANAESTHETIC WORKSTATION is provided with the display of pressure-volume loops, the loop graph shall have:

— DELIVERED VOLUME on the vertical axis;

— AIRWAY PRESSURE on the horizontal axis.

Positive values shall be represented to the top and the right of the display. Increases in DELIVERED VOLUME shall be represented as a positive value. The volume shall be reset to the origin at the beginning of each breath.

NOTE During controlled ventilation the loop will move anticlockwise. During spontaneous breathing the loop will move clockwise.

Check compliance by inspection.

201.106.2 Flow-volume loops

Positive values shall be represented to the top and the left of the display. Gas flow from the PATIENT (expiratory flow) and increases in DELIVERED VOLUME shall be represented as positive values. The volume shall be reset to the origin at the beginning of each breath. The zero point for DELIVERED VOLUME shall be to the right on the horizontal axis.

NOTE The loop will move clockwise so that inspiration is below the horizontal axis and expiration is above the horizontal axis.

The ANAESTHETIC WORKSTATION may be provided with an additional optional display configuration for the flow-volume loop specified by the MANUFACTURER.

Check compliance by inspection.

201.107 Clinical evaluation

A clinical evaluation shall be performed and documented.

Check compliance by inspection of the MANUFACTURER*'s documentation.*

202 Electromagnetic compatibility — Requirements and tests

IEC 60601-1-2:2007 applies.

203 General requirements for radiation protection in diagnostic X-ray equipment

IEC 60601-1-3 does not apply.

206 Usability

IEC 60601-1-6 applies except as follows:

206.6.2.2.2 PRIMARY OPERATING FUNCTIONS

Addition

For the ANAESTHETIC WORKSTATION and its individual components, if provided, the following shall be considered PRIMARY OPERATING FUNCTIONS:

aa) observing monitored ventilation parameters such as AIRWAY PRESSURES and volumes;

bb) observing respiratory gas concentrations such as inspired oxygen concentration (FiO_2), end tidal carbon dioxide ($etCO_2$) and anaesthetic agent concentration;

cc) setting volatile agent concentration;

dd) setting FRESH GAS flow and concentration;

ee) operating the O_2 flush;

ff) manually ventilating the PATIENT;

gg) setting the OPERATOR-adjustable AIRWAY PRESSURE control;

hh) setting ALARM LIMITS;

ii) inactivating ALARM SIGNALS;

jj) switching between ventilation modes;

kk) setting ventilation control parameters;

EXAMPLE Breathing frequency, tidal volume, PEEP, pressure support settings.

ll) suctioning the PATIENT;

mm) connecting the PATIENT to the PATIENT CONNECTION PORT;

nn) starting the ANAESTHETIC WORKSTATION from power off;

oo) starting the ANAESTHETIC WORKSTATION from standby mode;

pp) starting ANAESTHETIC VENTILATOR;

qq) connecting the ANAESTHETIC BREATHING SYSTEM to the FRESH-GAS OUTLET;

rr) if present, operation of a FRESH-GAS OUTLET switch (not more than one functional FRESH-GAS OUTLET);

ss) operation of the hypoxic mixture delivery selection PROTECTION DEVICE.

208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

IEC 60601-1-8:2006 applies except as follows:

208.5.2.2 * Technical description

Addition

The technical description shall include:

— a list of ALARM SYSTEMS and ALARM CONDITIONS to be tested by the user;

— the methods of verifying their correct function, e.g. by a built-in self test;

— the recommended frequency of VERIFICATION.

208.6.8.3 * Global indefinite ALARM SIGNAL inactivation states

Addition:

An ANAESTHETIC WORKSTATION and its individual components shall not be equipped with a means to initiate a global ALARM OFF while connected to a PATIENT.

208.6.8.4 * Termination of inactivation of ALARM SIGNALS

Addition:

The duration of AUDIO PAUSED for the HIGH PRIORITY ALARM CONDITIONs required by this International Standard shall not exceed 120 s without OPERATOR intervention.

Other priority alarms (LOW and MEDIUM PRIORITY ALARMS) may have longer AUDIO PAUSED durations.

208.6.12 * ALARM CONDITION logging

Amendment:

Replace the introductory sentence to the list by the following:

The ALARM SYSTEM of an ANAESTHETIC WORKSTATION shall be equipped with ALARM CONDITION logging for at least HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS.

NOTE This logging may be OPERATOR-configurable.

209 Requirements for environmentally conscious design

IEC 60601-1-9:2007 applies except as follows:

Addition:

NOTE Environmental aspects are summarized in Annex CC.

210 PROCESS requirements for the development of physiologic closed-loop controllers

IEC 60601-1-10:2007 applies.

211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the home healthcare environment

IEC 60601-1-11:2010 does not apply.

Annexes of IEC 60601-1:2005 apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS or their parts

201.C.1 Marking on the outside of ME EQUIPMENT and ME SYSTEMS or their parts

Additional requirements for marking on the outside of the ANAESTHETIC WORKSTATION and its individual components are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of the ANAESTHETIC WORKSTATION and its individual components

Description of marking	Subclause
For the ANAESTHETIC WORKSTATION and its individual components, marking with the safety sign for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005+TC1, Table D.2, number 10)	201.7.2.3
For the ANAESTHETIC WORKSTATION and its OPERATOR-detachable components or their packaging, marking with: — the year of manufacture except for single-use devices and those covered by a use-by date (see symbol 5.1.4 in ISO 15223-1:—) — if applicable, use-by date (see symbol 5.1.4 in ISO 15223-1:—)	201.7.2.101
For the OPERATOR-detachable components of the ANAESTHETIC WORKSTATION that are flow-direction sensitive, unless designed in such a way that prevents incorrect assembly, an arrow showing the direction of flow	201.7.2.102
For OPERATOR-accessible GAS-SPECIFIC inlet and outlet, the gas name or chemical symbol in accordance with Table 6 of ISO 5359:2008; if colour coding is used, compliance with Table 6 of ISO 5359:2008	201.7.2.103
For OPERATOR-accessible gas POWER SUPPLY outlets, the RATED output pressure and RATED flow rate	201.7.2.104
If relevant, marking of parts of the ANAESTHETIC WORKSTATION or its individual components that are in contact with gas to be inhaled by the patient and that contain phthalates, which are known to be carcinogenic, mutagenic or toxic to reproduction (see symbol in EN 15986[18])	201.7.2.105
For the ANAESTHETIC WORKSTATION and its individual components, the mass in NOMINAL configuration, in kilograms (kg)	201.7.2.106
For cylinder and pipeline pressure indicators, identification of the gas name or chemical symbol in accordance with Table 6 of ISO 5359:2008; if colour coding is used, compliance with Table 6 of ISO 5359:2008	201.7.2.107
Direction of the movement of a moving part where the direction of movement needs to be known in order to avoid a HAZARDOUS SITUATION	201.9.2.1
For non-metallic components made of antistatic or conductive materials, the CLEARLY LEGIBLE word “antistatic” or “conductive” or the equivalent in a language that is acceptable to the intended OPERATOR; these non-metallic components may additionally bear an indelible yellow coloured mark	201.102.1.1.1

Table 201.C.101 (*continued*)

Description of marking	Subclause
For inspiratory and expiratory ports of a CIRCLE ABSORBER ASSEMBLY, an arrow to indicate the intended direction of gas flow	201.102.1.1.4
For EXHAUST PORT connector that is OPERATOR-detachable without the use of a TOOL, the word “exhaust” or “AGS” or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol	201.102.5.2
For reservoir bag connection port, the word “bag” or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol	201.102.5.3
For ANAESTHETIC VENTILATOR port connector that is OPERATOR-detachable without the use of a TOOL, the word “ventilator” or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol	201.102.5.4
For gas sample return port, the word “gas return” or symbol ISO 7000-0795	201.102.5.7
For gas sample port, the words “gas sample” or symbol ISO 7000-0794	201.102.5.7
Marking that indicates that the RECEIVING SYSTEM of an ANAESTHETIC GAS SCAVENGING SYSTEM is suitable for use with high-flow-rate or low-flow-rate DISPOSAL SYSTEM, if the RECEIVING SYSTEM is physically discrete If colour coding is used to identify components as being specific for use with an ANAESTHETIC GAS SCAVENGING SYSTEM, it shall be magenta	201.103.1.1
Marking of the ANAESTHETIC VAPOUR DELIVERY SYSTEM with the safety sign for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005+TC1, Table D.2, number 10); such marking shall be CLEARLY LEGIBLE from the intended OPERATOR'S position	201.104.1.1
For the ANAESTHETIC VAPOUR DELIVERY SYSTEM, the maximum and minimum filling levels on the liquid level indicator, if the actual usable volume is not displayed	201.104.1.1
For the filling port of the ANAESTHETIC VAPOUR DELIVERY SYSTEM, the generic name of the anaesthetic agent in full spelling or in abbreviated form	201.104.6
For EXHAUST PORT connector that is OPERATOR-detachable without the use of a TOOL, the word “exhaust” or “AGS” or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol	201.105.6

201.C.3 Marking of controls and instruments

Additional requirements for marking of controls are found in Table 201.C.102.

Table 201.C.102 — Marking of controls

Description of marking	Subclause
For GAS-SPECIFIC flow rate adjustment control of an ANAESTHETIC GAS DELIVERY SYSTEM: — identification of the gas that it controls by the gas name or the chemical symbol in accordance with Table 6 of ISO 5359:2008; if colour coding is used, compliance with Table 6 of ISO 5359:2008 — indication on how to increase and decrease the gas flow rate; if applicable, the identification of the point of reference for reading the flow-rate indication	201.7.4.2
Marking of the oxygen flush control with one of the following: — "Oxygen Flush" — "O2 Flush" — "O2 +"	201.7.4.2
For OPERATOR-controlled mechanism that changes from reservoir bag to ANAESTHETIC VENTILATOR and vice-versa, marking of the words "bag" and "ventilator" or the equivalent in a language that is acceptable to the intended OPERATOR or an appropriate symbol	201.102.1.1.2
Marking the OPERATOR-controlled mechanism for excluding the absorbent from the gas pathway with the following: — the words "on" and "off", or the equivalent in a language that is acceptable to the intended OPERATOR, or — the words "absorber on" and "absorber off" or the equivalent in a language that is acceptable to the intended OPERATOR, or — the symbols shown in Figure 201.103	201.102.1.1.3
Graduation of FLOWMETERS or flow rate adjustment controls in litres per minute (l/min)	201.101.6.1
For the control activating the delivery of a specific vapour of a volatile anaesthetic agent, the generic name in full spelling or in abbreviated form as given in the following list: — Desflurane — "DES" — Enflurane — "ENF" — Halothane — "HAL" — Isoflurane — "ISO" — Sevoflurane — "SEV" For colour coding, see ISO 5360	201.104.1.1
On the ANAESTHETIC VAPOUR DELIVERY SYSTEM or its display for the calibrated range, the set concentration as well as the units of measure In addition, marking of the controls with "0" or "Off", or with both, if the "0" position is not also the "Off" position, or with "Standby" if "Off" is not provided	201.104.2.1

201.C.4 ACCOMPANYING DOCUMENTS, general

Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS of an ANAESTHETIC WORKSTATION and its individual components and accessories are found in Table 201.C.103.

Table 201.C.103 — ACCOMPANYING DOCUMENTS, general

Description of requirement	Subclause
Name or trade name and address of the MANUFACTURER, and where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale	201.7.9.1
Date of issue or the latest revision of the instructions for use	201.7.9.2.1
For the ANAESTHETIC WORKSTATION not supplied complete, in the instructions for use, as far as applicable, information about the MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES required by this International Standard and how to connect them	201.7.9.2.1
Statement to the effect that in case of failure of the ANAESTHETIC WORKSTATION, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT injury	201.7.9.2.2
Provision of at least one OPERATOR pre-use checklist	201.7.9.2.8
Information on the method of enabling the ANAESTHETIC WORKSTATION or its individual components including the MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES required by this International Standard	201.7.9.2.14
Conditions under which the measured values are displayed	201.7.9.2.14
Where an ANAESTHETIC WORKSTATION is not supplied complete, a statement to the effect that whoever assembles the ANAESTHETIC WORKSTATION from individual components shall provide the pre-use checklist for the ANAESTHETIC WORKSTATION	201.7.9.2.14
Where applicable, a statement to the effect that a malfunction of the MEDICAL GAS PIPELINE SYSTEM can cause one or more ANAESTHETIC WORKSTATIONS and other ANAESTHETIC WORKSTATION components connected to the MEDICAL GAS PIPELINE SYSTEM to stop their operation simultaneously; this is not applicable to ANAESTHETIC WORKSTATIONS that only use cylinders for gas supply	201.7.9.2.14
Where applicable, disclosure of the presence of all natural rubber latex-based components and their location (see Symbol 5.4.5 in ISO 15223-1:—)	201.7.9.2.14
Where applicable, whether the ANAESTHETIC WORKSTATION or its individual components is/are suitable for use in an MRI environment and any related restrictions	201.7.9.2.14
If an ANAESTHETIC WORKSTATION or its individual components is/are used for the treatment of children or treatment of pregnant or nursing women, the RESIDUAL RISK from phthalates that are carcinogenic, mutagenic or toxic to reproduction	201.7.9.2.14
For single-use ACCESSORIES to the ANAESTHETIC WORKSTATION or its individual components, disclosure of the RISKS associated with reusing; this information may be given upon request	201.7.9.2.14
Description of the functioning of the ANAESTHETIC WORKSTATION or its individual components after interruption of the POWER SUPPLY, and, where applicable, following a switchover to an INTERNAL ELECTRICAL POWER SOURCE; particular emphasis shall be placed on the flow rate and composition of the FRESH GAS and the behaviour of any OPERATOR-accessible gas POWER SUPPLY outlet under these circumstances	201.11.8.101
If the ANAESTHETIC WORKSTATION or its individual components has/have an INTERNAL ELECTRICAL POWER SOURCE: — the operational time of the INTERNAL ELECTRICAL POWER SOURCE when fully charged — the behaviour after a switchover to the INTERNAL ELECTRICAL POWER SOURCE — the behaviour while the INTERNAL ELECTRICAL POWER SOURCE is recharging	201.11.8.103

Table 201.C.103 (*continued*)

Description of requirement	Subclause
If the ANAESTHETIC WORKSTATION is not equipped with the following MONITORING EQUIPMENT, ALARM SYSTEMS, and PROTECTION DEVICES, a statement to the effect that the ANAESTHETIC WORKSTATION is to be equipped with these items, before being put into service and a description of how to connect these items: — AIRWAY PRESSURE MONITORING EQUIPMENT complying with 201.12.4.109 — MAXIMUM LIMITED PRESSURE PROTECTION DEVICE complying with 201.102.2.1 (ANAESTHETIC BREATHING SYSTEM) or 201.105.2.1 (ANAESTHETIC VENTILATOR) — adjustable pressure limitation PROTECTION DEVICE complying with 201.102.2.2 (ANAESTHETIC BREATHING SYSTEM) or 201.105.2.2 (ANAESTHETIC VENTILATOR) — exhaled volume MONITORING EQUIPMENT complying with 201.12.4.104 — ALARM SYSTEM with ANAESTHETIC BREATHING SYSTEM integrity ALARM CONDITION complying with 201.12.4.105 — carbon dioxide MONITORING EQUIPMENT complying with 201.12.4.103.1 — oxygen MONITORING EQUIPMENT complying with 201.12.4.103.2 — anaesthetic agent MONITORING EQUIPMENT with halogenated agent MONITORING EQUIPMENT if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM complying with 201.12.4.103.3 — ANAESTHETIC BREATHING SYSTEM continuing-positive-pressure ALARM CONDITION complying with 201.12.106 — oxygen supply failure ALARM SYSTEM and PROTECTION DEVICE complying with 201.12.4.107.1 and 201.1.24.107.2 respectively — hypoxic mixture delivery selection PROTECTION DEVICES complying with 201.12.4.107.3 — PROTECTION DEVICE for the workplace environment (ANAESTHETIC GAS SCAVENGING SYSTEM) if the ANAESTHETIC GAS DELIVERY SYSTEM IS equipped with means to deliver nitrous oxide or is designed to be equipped with AN ANAESTHETIC VAPOUR DELIVERY SYSTEM complying with 201.12.4.108 From MANUFACTURERS of individual components information regarding how to connect these items to the ANAESTHETIC WORKSTATION	201.12.4.102
A statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with halogenated anaesthetic agent MONITORING EQUIPMENT complying with ISO/IEC 80601-2-55 before the ANAESTHETIC WORKSTATION is put into service and a description of how to connect it, if the ANAESTHETIC GAS DELIVERY SYSTEM is not so equipped From MANUFACTURERS of halogenated anaesthetic agent MONITORING EQUIPMENT, information regarding how to connect that item to the ANAESTHETIC WORKSTATION, upon request	201.12.4.103.3
For exhaled volume MONITORING EQUIPMENT, the accuracy of the displayed exhaled volume, if the accuracy of the displayed exhaled volume exceeds the values specified in this International Standard	201.12.4.104.1
A statement to the effect that the ANAESTHETIC BREATHING SYSTEM is to be provided with an ALARM SYSTEM that includes an ALARM CONDITION that indicates when the AIRWAY PRESSURE exceeds the continuing positive pressure ALARM LIMIT before the ANAESTHETIC BREATHING SYSTEM is put into service, if the ANAESTHETIC BREATHING SYSTEM is not so equipped Unless the ALARM SYSTEM that includes an ALARM CONDITION that indicates when the AIRWAY PRESSURE exceeds the continuing positive pressure ALARM LIMIT is an integral	201.12.4.106

Table 201.C.103 (*continued*)

Description of requirement	Subclause
part of the ANAESTHETIC BREATHING SYSTEM, information on how to connect it	201.12.4.106
Disclosure of the behaviour of the ANAESTHETIC GAS DELIVERY SYSTEM under the conditions specified for the oxygen supply failure PROTECTION DEVICE in this International Standard	201.12.4.107.2
For the ANAESTHETIC WORKSTATION a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with an ANAESTHETIC GAS SCAVENGING SYSTEM complying with this International Standard before being put into service The instructions for use of the ANAESTHETIC WORKSTATION and the ANAESTHETIC GAS SCAVENGING SYSTEM shall disclose how to connect the ANAESTHETIC GAS SCAVENGING SYSTEM	201.12.4.108
For the ANAESTHETIC GAS DELIVERY SYSTEM: a) a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM complies with this International Standard b) unless the ANAESTHETIC BREATHING SYSTEM is integral to the ANAESTHETIC GAS DELIVERY SYSTEM or ANAESTHETIC WORKSTATION, a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM or ANAESTHETIC WORKSTATION is intended to be used with an ANAESTHETIC BREATHING SYSTEM that complies with this International Standard c) instructions for testing for correct assembly and connection of each gas supply d) if applicable, the medical gas supply pressure(s) at which the ANAESTHETIC GAS DELIVERY SYSTEM will cease to deliver gas as specified e) unless the ANAESTHETIC BREATHING SYSTEM is an integral part of the ANAESTHETIC GAS DELIVERY SYSTEM, information on how to connect an ANAESTHETIC BREATHING SYSTEM f) if the ANAESTHETIC GAS DELIVERY SYSTEM is equipped with a means to deliver nitrous oxide or is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM is to be used with an ANAESTHETIC GAS SCAVENGING SYSTEM complying with this International Standard g) if the ANAESTHETIC GAS DELIVERY System is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM used with the ANAESTHETIC GAS DELIVERY SYSTEM needs to comply with this International Standard h) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the ANAESTHETIC GAS DELIVERY SYSTEM is to be used with halogenated anaesthetic agent MONITORING EQUIPMENT complying with ISO/IEC 80601-2-55 i) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an ANAESTHETIC VENTILATOR, a statement to the effect that the ANAESTHETIC VENTILATOR shall comply with the requirements of this International Standard j) a statement to the effect that the ANAESTHETIC WORKSTATION is intended for use with non-flammable anaesthetic agents as specified in this International Standard and that flammable anaesthetic agents such as diethyl ether and cyclopropane are not to be used in the ANAESTHETIC WORKSTATION	201.101.1.1

Table 201.C.103 (*continued*)

Description of requirement	Subclause
For the ANAESTHETIC BREATHING SYSTEM and its individual components:	201.102.1.2
a) a diagram of the complete ANAESTHETIC BREATHING SYSTEM identifying its components and their recommended location(s) b) a statement to the effect that the ANAESTHETIC BREATHING SYSTEM or its components comply with this International Standard c) unless the ANAESTHETIC BREATHING SYSTEM is an integral part of the ANAESTHETIC GAS DELIVERY SYSTEM or ANAESTHETIC WORKSTATION, information on how to connect an ANAESTHETIC BREATHING SYSTEM d) the internal compliance, expressed as a volume in millilitres (ml) at a pressure of 30 hPa (30 cmH_2O), with any reservoir bag excluded e) unless permanently mounted, the recommended orientation of the ANAESTHETIC BREATHING SYSTEM and its components and details of the effects of other orientations on performance f) information on any means of pressure relief, including pressure/flow rate characteristics g) a statement of known compatibility with gases and anaesthetic agents h) a statement regarding the suitability for use with flammable anaesthetic agents, i.e., CATEGORY AP or CATEGORY APG i) the instructions for use of ANAESTHETIC BREATHING SYSTEM components not integrated into the ANAESTHETIC BREATHING SYSTEM shall include a diagram showing the recommended locations of such ANAESTHETIC BREATHING SYSTEM components, the location of the FRESH-GAS INLET and the ventilator inlet j) the instructions for use of EXHAUST VALVES not integrated into the ANAESTHETIC BREATHING SYSTEM shall describe the pressure/flow-rate characteristics of the EXHAUST VALVE including the opening pressure and the pressure drop at a flow rate of 30 l/min at BTPS k) the instructions for use of a CIRCLE ABSORBER ASSEMBLY and its components not integrated into the ANAESTHETIC BREATHING SYSTEM shall identify the carbon dioxide absorbent recommended for use and the volume of the absorbent container expressed in millilitres (ml) l) for breathing ACCESSORIES intended to be assembled by the OPERATOR, their resistance and compliance m) for an ANAESTHETIC BREATHING SYSTEM supplied separately, a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with an AIRWAY PRESSURE MONITORING EQUIPMENT complying with this International Standard (see 201.12.4.109) before being put into service and a description on how to connect that item	201.102.1.2 see also 201.102.8.2
For the ANAESTHETIC BREATHING SYSTEM: — the maximum FRESH-GAS INLET flow rate if this is greater than 10 l/min (±1 l/min) — the inspiratory and expiratory pressure/flow rate characteristics including the pressure at 60 l/min	201.102.7
For an EXHAUST VALVE not integrated into the ANAESTHETIC BREATHING SYSTEM, disclosure of the following: — the opening pressure — the pressure/flow-rate characteristics — the pressure drop with any EXHAUST VALVE control fully open at a flow rate of 30 l/min — for an EXHAUST VALVE that can be fully closed, the leakage to atmosphere in the fully closed position at a pressure of 30 hPa (30 cmH_2O)	201.102.8.2 see also 201.102.1.2 j)
For the absorbent bypass mechanism, disclosure of the proportion of gas that does not pass through the absorbent with the bypass control at intermediate settings, if so equipped, and at the “on” setting	201.102.9.2
Description of the inspiratory and expiratory pressure/flow rate characteristics of the CIRCLE ABSORBER ASSEMBLY, including the pressure at 60 l/min	201.102.9.3

Table 201.C.103 (*continued*)

Description of requirement	Subclause
Information as to how the OPERATOR can check the function of inspiratory and expiratory valves	201.102.10.1
For inspiratory and expiratory UNIDIRECTIONAL VALVES that are not integrated in the ANAESTHETIC BREATHING SYSTEM, disclosure of the pressure/flow-rate characteristics of the valves under both wet and dry conditions, including the pressure drop at a flow rate of 60 l/min	201.102.10.3
For the ANAESTHETIC GAS SCAVENGING SYSTEM: — a statement to the effect that the ANAESTHETIC GAS SCAVENGING SYSTEM complies with this International Standard — the RATED MAXIMUM and MINIMUM EXHAUST FLOW RATE of the disposal system with which the TRANSFER SYSTEM and RECEIVING SYSTEM are intended to be used	201.103.1.2
For the ANAESTHETIC VAPOUR DELIVERY SYSTEM: a) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM complies with this International Standard b) a statement to the effect that an ANAESTHETIC WORKSTATION used with this ANAESTHETIC VAPOUR DELIVERY SYSTEM needs to comply with this International Standard c) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM is to be used with halogenated anaesthetic agent MONITORING EQUIPMENT complying with ISO/IEC 80601-2-55 d) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM is to be used with an ANAESTHETIC GAS DELIVERY SYSTEM complying with this International Standard e) a statement to the effect that the ANAESTHETIC VAPOUR DELIVERY SYSTEM is to be used with an ANAESTHETIC GAS SCAVENGING SYSTEM complying with this International Standard f) the performance of the ANAESTHETIC VAPOUR DELIVERY SYSTEM including the effects of variation in ambient temperature, ambient pressure, resistance, tilting, back pressure, subatmospheric pressure, input flow rate and gas composition over the range of operating conditions specified in the instructions for use g) the carrier gas, gas flow rate(s) and analytical technique(s) recommended for measuring the output of the ANAESTHETIC VAPOUR DELIVERY SYSTEM h) a statement to the effect that the vaporizer should not be used between zero and the first calibration, if applicable i) the volume at the maximum and minimum fill levels and the total capacity	201.104.1.2 201.12.4.103.3
If the ANAESTHETIC VAPOUR DELIVERY SYSTEM should not be used between "Off" and the first graduation above zero, an appropriate statement	201.104.2.1
Disclosure of the volume of liquid anaesthetic agent required to fill the reservoir of the ANAESTHETIC VAPOUR DELIVERY SYSTEM to the maximum filling level, and the total capacity	201.104.6

Table 201.C.103 (*continued*)

Description of requirement	Subclause
For the ANAESTHETIC VENTILATOR: a) a statement to the effect that the ANAESTHETIC VENTILATOR complies with this International Standard b) a statement to the effect that the ANAESTHETIC VENTILATOR is intended to be used with an ANAESTHETIC BREATHING SYSTEM that complies with this International Standard c) unless the ANAESTHETIC VENTILATOR is an integral part of the ANAESTHETIC WORKSTATION, information on how to connect to an ANAESTHETIC WORKSTATION and ANAESTHETIC BREATHING SYSTEM d) the operational characteristics of the ANAESTHETIC VENTILATOR including, where applicable, the following: 1) range of DELIVERED VOLUMES (tidal and minute) 2) range of cycling frequency 3) range of I/E ratios 4) range of values that can be set as the maximum pressure at the PATIENT CONNECTION PORT during NORMAL USE in the inspiratory phase and the means by which that maximum pressure is ensured (e.g. pressure cycling, pressure limitation) 5) inspiratory flow rate and pressure characteristics 6) modes of cycling 7) the minimum pressure at the PATIENT CONNECTION PORT (during NORMAL USE and under single fault condition) 8) PEEP range 9) if there is a facility for subatmospheric pressure in the expiratory phase, the limiting pressure and generated pressure 10) characteristics of the means used for initiation of the inspiratory phase, e.g. PATIENT trigger 11) interdependence of controls 12) if applicable, a statement that the ANAESTHETIC VENTILATOR compensates for ANAESTHETIC BREATHING SYSTEM compliance and a description of the method of compliance compensation e) any restrictions on the location and/or sequence of components within the ANAESTHETIC BREATHING SYSTEM as they relate to the ANAESTHETIC VENTILATOR f) the range of internal volume of any ANAESTHETIC BREATHING SYSTEM ACCESSORIES or other components or subassemblies recommended by the MANUFACTURER g) for an ANAESTHETIC VENTILATOR supplied separately, a statement to the effect that the ANAESTHETIC WORKSTATION is to be provided with an AIRWAY PRESSURE MONITORING EQUIPMENT complying with this International Standard (see 201.12.4.109) before being put into service and a description on how to connect that item	201.105.1
A statement to the effect that the ANAESTHETIC BREATHING SYSTEM is to be provided with a PROTECTION DEVICE to limit the pressure at the PATIENT CONNECTION PORT to an OPERATOR-adjustable pressure complying with this International Standard before the ANAESTHETIC WORKSTATION is put into service and description of how to connect that item to the ANAESTHETIC WORKSTATION if the ANAESTHETIC VENTILATOR is not so equipped	201.105.2.2
A statement to the effect that the ANAESTHETIC VENTILATOR is to be provided with an AIRWAY PRESSURE MONITORING EQUIPMENT complying with this International Standard before being put into service and description of how to connect that item, if the ANAESTHETIC VENTILATOR is not equipped with an AIRWAY PRESSURE MONITORING EQUIPMENT From MANUFACTURERS of the AIRWAY PRESSURE MONITORING EQUIPMENT, information regarding how to connect that item to the ANAESTHETIC WORKSTATION, upon request	201.105.3
Disclosure of OPERATOR actions necessary to ensure the continued supply of FRESH GAS to or ventilation of the PATIENT under POWER SUPPLY failure conditions	201.105.5

201.C.4 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for information to be included in the technical description of an ANAESTHETIC WORKSTATION and its individual components are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
For ANAESTHETIC WORKSTATIONS intended to be mounted to a wall or a ceiling pendant and that are not considered mobile equipment and consequently need not comply with the requirement on moving over a threshold in 201.9.4.2.4.3, the technical description shall contain a warning to the effect of "Warning: This device, when removed from its wall or ceiling mount, does not meet the stability requirements of ISO 80601-2-13 and IEC 60601-1 respectively. Special caution has to be taken." The technical description shall contain any additional handling instructions necessary to allow transport with an acceptable RISK according to the RISK MANAGEMENT FILE	201.7.9.3.102
Description of the maximum weight of components, as well as the height of and length of arms on which these components may be mounted on the ANAESTHETIC WORKSTATION or its individual components so as not to compromise the stability requirements tested in IEC 60601-1:2005, Clause 9	201.7.9.3.101
For the ANAESTHETIC GAS DELIVERY SYSTEM, — pressure and flow rate characteristics of any gas POWER SUPPLY outlet throughout the RATED range of inlet pressure — operating characteristics and location of any pressure relief PROTECTION DEVICES	201.101.1.2
For the ANAESTHETIC GAS SCAVENGING SYSTEM, description of how to measure the leakage of the TRANSFER and RECEIVING SYSTEM	201.103.3.1.5
For alarms, — a list of ALARM SYSTEMS and ALARM CONDITIONS to be tested by the user — the methods of verifying their correct function, e.g. by a built-in self test — the recommended frequency of VERIFICATION	208.5.2.2

Annex D
(informative)

Symbols on marking

IEC 60601-1:2005, Annex D applies, except as follows:

Addition:

Table 201.D.2.101 — Additional symbols on marking

No.	Symbol	Reference	Title
1	yyyy/mm	ISO 7000-2607	Use-by date
2	LATEX	Application of ISO 7000-2725	Contains or presence of natural rubber latex
3	PHT	Application of ISO 7000-2725	Contains or presence of phthalate
4		ISO 7000-0794	Input; entrance
5		ISO 7000-0795	Output; exit

Table 201.D.2.101 (*continued*)

No.	Symbol	Reference	Title
6	(“on”) (“off”)	Figure 201.103	Absorbent bypass control markings

Additional annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the subclauses in this International Standard. The numbering is, therefore, not consecutive.

Subclause 201.1.1 Scope

Table AA.1 illustrates the configuration of an ANAESTHETIC WORKSTATION and provides a summary of RISK CONTROL measures for an ANAESTHETIC WORKSTATION for various actuators and associated MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES. They allow easy reference of applicable subclauses and shows prerequisite conditions for specific applications.

Table AA.1 — Summary of RISK CONTROL measures for an ANAESTHETIC WORKSTATION

Risk control measure	Monitor or monitoring equipment and alarm systems																	Protection devices					
	Power supply failure	Oxygen supply failure	Oxygen concentration		Anaesthetic agent concentration			Airway pressure				Exhaled volume		Anaesthetic breathing system	Carbon dioxide concentration			Oxygen supply failure	Hypoxic mixture selection	Anaesthetic gas scavenging system	Maximum limited pressure	Adjustable pressure limitation	Subatmospheric pressure limitation
	A	A	M	L	M	L	H	M	L	H	CPP[e]	M	L	A	M	L	H	P	P	P	P	P	P
Subclause 201.x	11.8.102	12.4.102 12.4.107.1	12.4.102 12.4.103.2	12.4.102 12.4.103.2	12.4.102 12.4.103.3	12.4.102 12.4.103.3	12.4.102 12.4.103.3	12.4.102 12.4.109	12.4.102 12.4.109	12.4.102 12.4.109	12.4.102 12.4.106	12.4.102 12.4.104.1	12.4.102 12.4.104.2	12.4.102 12.4.105	12.4.102 12.4.103.1	12.4.102 12.4.103.1	12.4.102 12.4.103.1	12.4.102 12.4.107.2	12.4.102 12.4.107.3	12.4.102 12.4.108	12.4.102 102.2.1 105.2.1	12.4.102 102.2.2 105.2.2	105.8
Actuator																							
Driving power - electric - pneumatic	+ +	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -
ANAESTHETIC GAS DELIVERY SYSTEM																							
- oxygen	-	+[c]	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
- air	-	+[c]	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
- premixed[a]	-	+[c]	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
- others[b]	-	-	+	+	-	-	-	-	-	-	-	-	-	-				+	+	+	-	-	-
ANAESTHETIC BREATHING SYSTEM	-	-	+	+	-	-	-	+	R	+	+	+[d]	+	+	+	+	+	-	-	-	+	+	-
CIRCLE BREATHING SYSTEM	-	-	+	+	-	-	-	+	R	+	+	+	+	+	+	+	+	-	-	-	+	+	-
ANAESTHETIC VAPOUR DELIVERY SYSTEM	-	-	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-

Table AA.1 (*continued*)

Risk control measure	Monitor or monitoring equipment and alarm systems																	Protection devices					
	Power supply failure	Oxygen supply failure	Oxygen concentration		Anaesthetic agent concentration			Airway pressure				Exhaled volume		Anaesthetic breathing system	Carbon dioxide concentration			Oxygen supply failure	Hypoxic mixture selection	Anaesthetic gas scavenging system	Maximum limited pressure	Adjustable pressure limitation	Subatmospheric pressure limitation
	A	A	M	L	M	L	H	M	L	H	CPP[e]	M	L	A	M	L	H	P	P	P	P	P	P
Subclause 201.x	11.8.102	12.4.102 12.4.107.1	12.4.102 12.4.103.2	12.4.102 12.4.103.2	12.4.102 12.4.103.3	12.4.102 12.4.103.3	12.4.102 12.4.103.3	12.4.102 12.4.109	12.4.102 12.4.109	12.4.102 12.4.109	12.4.102 12.4.106	12.4.102 12.4.104.1	12.4.102 12.4.104.2	12.4.102 12.4.105	12.4.102 12.4.103.1	12.4.102 12.4.103.1	12.4.102 12.4.103.1	12.4.102 12.4.107.2	12.4.102 12.4.107.3	12.4.102 12.4.108	12.4.102 102.2.1 105.2.1	12.4.102 102.2.2 105.2.2	105.8
ANAESTHETIC VENTILATOR	+	+	-	-	-	-	-	+	R	+	+	+	+	+	+	+	+	-	-	-	+	+	+

Key

\+ always mandatory; R recommendation; - no requirement;

A ALARM CONDITION; H high level ALARM CONDITION; L low level ALARM CONDITION

M quantitative MONITORING EQUIPMENT; P PROTECTION DEVICE

[a] Premixed gases of 50 % N_2O and 50 % O_2.

[b] Others might include N_2O.

[c] Mandatory only if primary or sole source of oxygen/oxygen-enriched air.

[d] Inspiratory volume monitoring permissible with manual or spontaneous ventilation.

[e] Continuous positive pressure ALARM CONDITION.

In order to clarify the applicability of this International Standard, Table AA.2 identifies typical use environments of ANAESTHETIC WORKSTATIONS with the corresponding resources and use scenarios.

Table AA.2 — Use environments

Use environment	Resources	Use scenario	Applicable standard
Hospital	Central gas supply with O_2, N_2O and air backup Electrical power with backup ANAESTHETIC WORKSTATION with backup, ventilator, vaporizers, etc. Extensive patient monitoring In-house medical faculty Climate control Anaesthetic gas scavenging In-house pharmacy Cardiopulmonary resuscitation (CPR) equipment and OPERATORS Hospital supply stockroom	Anaesthetist/anaesthesiologist or nurse anaesthetist Multi-tasking when supervising registered nurse anaesthetists (CRNA) or residents	ISO 80601-2-13
Physician's office	Gas supply with limited backup Electrical power Anaesthetic equipment PATIENT MONITORING EQUIPMENT In-house surgeon CPR equipment and OPERATOR Climate control Limited pharmacy and supplies	Anaesthetist/anaesthesiologist or nurse anaesthetist	ISO 80601-2-13
Dental office	Gas supply (premixed O_2/N_2O or O_2-N_2O mixer) Electrical power Analgesic apparatus Climate control	Dentist Multi-tasking Patient interaction	ISO 80601-2-13
Emergency areas/ rescue vehicles	Portable gas supply (O_2) Portable electrical power Consultant via phone CPR equipment and operator Portable anaesthesia machine Mask and self-inflating bag Portable ventilator Portable patient monitors Portable pharmacy	Paramedic Multi-tasking Stressed High workload Time pressure	ISO 80601-2-13
Civil emergencies, disaster areas and areas with limited logistical support	Electric power via diesel/gasoline generator OXYGEN CONCENTRATOR and bottled O_2 Oxygen FLOWMETER Anaesthesia system Non-rebreathing anaesthetic system Draw-over vaporizer Ventilator (manual or mechanical) Limited pharmacy Limited patient and machine monitoring	Anaesthetist/anaesthesiologist or trained technician Single-tasking Adverse environment	ISO 8835-7

Administering an anaesthetic is in itself hazardous. RISKS associated with administering an anaesthetic are not covered by this International Standard

The use of flammable anaesthetics, as determined by Annex BB, has diminished to a point where it was agreed not to consider adding specific requirements to this International Standard to address the associated HAZARDS.

Subclause 201.4.3 ESSENTIAL PERFORMANCE

The loss of oxygen delivery could result in an unacceptable RISK to the PATIENT. The ANAESTHETIC WORKSTATION needs to make every attempt to continue oxygen delivery as long as possible under as many fault conditions as possible.

All PATIENTS who receive gas delivered by an ANAESTHETIC WORKSTATION depend on a sufficient amount of oxygen in this gas. When an ANAESTHETIC GAS DELIVERY SYSTEM is used with a non-rebreathing system, it is sufficient to ensure non-hypoxic concentrations in the delivered FRESH GAS. In certain configurations of circle systems used with low flow techniques only measuring the inspired oxygen concentration provides a sufficient means to ensure this ESSENTIAL PERFORMANCE.

There is no dispute that delivering excessive concentrations of volatile anaesthetic agents poses a RISK to the PATIENT. Therefore, avoiding delivery of high concentrations is considered to be ESSENTIAL PERFORMANCE for an ANAESTHETIC WORKSTATION to ensure that the delivery of high concentrations is avoided.

The loss of controlled ventilation to the PATIENT may result in an unacceptable RISK to the PATIENT. Identifying AIRWAY PRESSURE monitoring (and associated alarms) as ESSENTIAL PERFORMANCE will provide the OPERATOR with indications of ventilation. In addition to the designation of these items as ESSENTIAL PERFORMANCE, this International Standard requires that the instructions for use contain a statement to the effect that, in case of ANAESTHETIC WORKSTATION failure, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT injury. This International Standard also provides examples of an alternative means of ventilation as well as an accompanying rationale.

The combination of RISK mitigation methods described above is believed to be sufficient enough to make the residual RISK level acceptable.

Attention is drawn to additional ESSENTIAL PERFORMANCE requirements given in other particular standards.

Subclause 201.4.10.101 Requirements for pneumatic power input

An ANAESTHETIC WORKSTATION designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its RATED range of supply pressures; these pressures can only be maintained if the ANAESTHETIC WORKSTATION in NORMAL CONDITION does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that these ANAESTHETIC WORKSTATIONS will be designed to prevent an unacceptable RISK under possible SINGLE FAULT CONDITIONS of the pressurized gas supply.

Pressurized medical gas supplies, including MEDICAL GAS PIPELINE SYSTEMS and cylinder PRESSURE REGULATORS conforming to current relevant standards, supply GAS-SPECIFIC terminal outlets at a pressure that is within an internationally agreed pressure range of 280 kPa to 600 kPa under NORMAL CONDITION. It is expected that ANAESTHETIC WORKSTATIONS will operate to their declared specification with any supply pressure within this range.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, MEDICAL GAS PIPELINE SYSTEMS supplying compressed MEDICAL GASES through GAS-SPECIFIC terminal outlets are designed so that they can maintain this pressure at the input connection of gas-powered devices whilst supplying steady-state flows up to 60 l/min at a single outlet connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the TERMINAL UNIT and the hose assembly connecting the device to the pipeline.

The MEDICAL GAS PIPELINE SYSTEM is also required to be capable of supplying sufficient gas so that this flow can be drawn from a predetermined number of adjacent TERMINAL UNITS simultaneously. The actual number will have been determined during the design and installation of the MEDICAL GAS PIPELINE SYSTEM by the application of a “diversity factor”, a factor agreed between the supplier and RESPONSIBLE ORGANIZATION to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the MEDICAL GAS PIPELINE SYSTEM is capable of supplying an average flow of 60 l/min to the required proportion of terminal outlets. However, if the flow demand from many adjacent ANAESTHETIC WORKSTATIONS exceeds 60 l/min there is an increased possibility that the ANAESTHETIC WORKSTATION input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the TERMINAL UNIT and input hose (also because of the flow-drop characteristic in the case of PRESSURE REGULATORS supplying a single terminal outlet).

In addition to steady-state flows of 60 l/min, the switching of the internal pneumatic system and the operation of a PATIENT demand system can result in an ANAESTHETIC WORKSTATION requiring fast transient input flows far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize pressure drop, such fast transient demands can generally be accommodated from the gas stored locally within the pipework of the MEDICAL GAS PIPELINE SYSTEM. There can be temporary pressure drops of the input pressure at the inlet of the ANAESTHETIC WORKSTATION, to below 280 kPa, due to any transient flows in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the MANUFACTURER. MANUFACTURERS need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their ANAESTHETIC WORKSTATION when used with recommended supply hose configurations and when connected to alternative GAS-SPECIFIC terminal outlets such as those fitted to cylinder PRESSURE REGULATORS conforming to ISO 10524-1.

The permitted maximum average flow of 60 l/min stated in this International Standard is greater than the test flow used during the commissioning of MEDICAL GAS PIPELINE SYSTEMS. In itself, this should be of no concern because the specific conditions specified for the test do not allow a direct comparison between the two values. The Technical Committee responsible for standards on MEDICAL GAS PIPELINE SYSTEMS, ISO TC 121/SC 6, in consultation with ISO TC 121/SC 1 and ISO TC 121/SC 3, agreed to the 60 l/min average flow value, and also the 200 l/min for up to 3 s transient flows, during the preparation of the first edition of the current series of International Standards for MEDICAL GAS PIPELINE SYSTEMS and were aware of the need to satisfy that specification when finalizing the MEDICAL GAS PIPELINE SYSTEM test requirements.

MANUFACTURERS should be aware that other standards on MEDICAL GAS SUPPLY SYSTEMS permit the fitting of GAS-SPECIFIC terminal outlets to spur systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101.2 Gas flow rate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~ 37 °C) irrespective of the temperature of the gas delivered by an ANAESTHETIC VENTILATOR. The volume of a given amount of gas increases by about 13,5 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurized gas to medical equipment, including ANAESTHETIC VENTILATORS, follow engineering conventions and specify gas quantities and flow rates at STPD conditions. This practice is followed in this International Standard for all requirements concerning gas input.

However, ANAESTHETIC VENTILATORS complying with this International Standard are likely to be inflating the PATIENT'S lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered from an ANAESTHETIC VENTILATOR. With a standard temperature of 0 °C, 1 l of gas referenced to STPD can expand the lungs by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different ANAESTHETIC VENTILATORS, it is essential that the information for all ANAESTHETIC VENTILATORS be referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, BTPS is the appropriate set of reference conditions to use.

In ANAESTHETIC VENTILATORS a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore, the necessary corrections depend on the type of flow transducer. When a pressure correction is required, this can be adequately estimated. The necessary corrections also depend on the location of the flow transducer in the ANAESTHETIC BREATHING SYSTEM. The humidity of the gas can be zero when the transducer measures the inspired flow inside the ANAESTHETIC VENTILATOR. When, however, the flow transducer is located at the Y-PIECE, the relative humidity can be anything up to 100 %. When a HEAT AND MOISTURE EXCHANGER is used for humidification, the output of the flow-transducer depends on whether it is located distal or proximal to the HEAT AND MOISTURE EXCHANGER. With a turbine-based ANAESTHETIC VENTILATOR that uses ambient air, the humidity of the drawn-in air can be unknown to the ANAESTHETIC VENTILATOR. All these effects together will inevitably introduce some errors in the conversion of the measured flow signal to BTPS reference conditions. However, these errors are only in the range of several percent.

Subclause 201.7.2.3 Consult ACCOMPANYING DOCUMENTS

Following the instructions for use is considered a mandatory action for the safe operation of an ANAESTHETIC WORKSTATION and its individual components.

Subclause 201.7.2.104 OPERATOR-accessible gas POWER SUPPLY outlet

Connecting pneumatically driven equipment to a gas POWER SUPPLY outlet of an ANAESTHETIC WORKSTATION can cause the internal pressure in the ANAESTHETIC WORKSTATION to fall below a level where it may not function properly.

Subclause 201.7.2.106 Marking with mass

Modern ANAESTHETIC WORKSTATIONS are quite heavy, especially if fully equipped with various components required in this International Standard and other devices needed for routine clinical use. ANAESTHETIC WORKSTATIONS are, by definition, mobile devices that are intended to be moved between operating rooms and taken to maintenance locations by the clinical user or hospital technicians. Marking the device with its mass allows users to select a route more convenient for heavy equipment or to call for assistance to help with the transport.

Subclause 201.7.4.2 Control devices

The marking of GAS-SPECIFIC flow rate adjustment controls is required to be consistent with that used on the corresponding gas supplies and pressure indicators. This minimizes the likelihood of confusion.

In an ANAESTHETIC WORKSTATION, especially with controls for the flow of gases, it is important that the OPERATOR is able to identify immediately what gas flow setting he/she is about to change. Colour coding is helpful and should comply with International Standards.

Traditionally, the direction to increase a setting is different for mechanical (anticlockwise) and electronic (clockwise) functions. This requirement aims to avoid confusing OPERATORS.

Subclause 201.7.4.3 Unit of measure

Additional information can be found in the rationale to 201.5.101.2.

Subclause 201.7.9.2.2 Warnings and safety notices

Even with ANAESTHETIC WORKSTATIONS that are safe under SINGLE FAULT CONDITIONS, a failure to ventilate the PATIENT with adequate concentrations and volumes is possible. Protection of the PATIENT in such an infrequent but possibly fatal situation requires the immediate access to an alternative means of ventilation.

Subclause 201.7.9.2.8 Start-up PROCEDURE

For many years, pre-use checklists described those checks necessary for safe operation. These checks are to be performed by the OPERATOR prior to use either every day or before each case. The less integrated an ANAESTHETIC WORKSTATION is, the more important a thorough pre-use check becomes to ensure that all necessary equipment is present, correctly connected, switched on and fully functional. An essential part is verifying that ALARM SYSTEMS function properly.

Most modern ANAESTHETIC WORKSTATIONS incorporate PEMS that perform some of the pre-use checks. Almost all MONITORING EQUIPMENT test all its ALARM SYSTEMS. Here it is important to inform the OPERATOR or RESPONSIBLE ORGANIZATION which checks are automatically performed by the ANAESTHETIC WORKSTATION to enable the OPERATOR to adapt checklists.

Additional, important information is the situation, frequency or point in time when automatic test PROCEDURES have to be started by the OPERATOR.

Subclause 201.8.11.3.101 Additional requirements for POWER SUPPLY CORDS

Designing an ANAESTHETIC WORKSTATION or its individual components with a fixed POWER SUPPLY cord mitigates the RISK of unintentional interruptions of SUPPLY MAINS, which could result in interruption of the operation of the ANAESTHETIC WORKSTATION or its individual components. If such interruption persists too long or restarting the ANAESTHETIC WORKSTATION or its individual components requires considerable OPERATOR interaction, the PATIENT is exposed to additional RISK. However, a fixed POWER SUPPLY CORD raises other RISKS like damaging the POWER SUPPLY CORD, the MAINS CONNECTOR or the APPLIANCE INLET, or injuries due to falls of personnel.

As many modern ANAESTHETIC WORKSTATIONS are equipped with uninterruptable POWER SUPPLY (UPS), backup batteries or quick start PROCEDURES, the RISKS from SUPPLY MAINS interruptions are greatly reduced. If such features are provided, a DETACHABLE POWER SUPPLY CORD is considered to increase the overall safety.

Subclause 201.9.2.102 Lighting

Insufficient illumination of work areas, overly bright light, reflections and flashing effects can stress OPERATORS more than necessary, thus leading to more frequent use errors and HAZARDS for the OPERATORS themselves.

Subclause 201.9.2.103 Integrated seating

Even if unlikely, it is not unthinkable that an ANAESTHETIC WORKSTATION might include a seat for the anaesthetist. As already standard for common machinery, certain minimum safety requirements also apply here.

Subclause 201.9.2.104 Arrangement of control positions

Even if unlikely today, it can be imagined that ceiling pendants, on which an ANAESTHETIC WORKSTATION is mounted, might be moved electrically. This would be an example for a system where a RISK would arise if more than one control for the movement were provided.

Subclause 201.11.8.101 General requirements

To continue adequate ventilation and therapy of the PATIENT, it is important that the OPERATOR understands the behaviour of the ANAESTHETIC WORKSTATION or its individual components after interruption of the POWER SUPPLY.

When a gas POWER SUPPLY fails, it is vital to know whether gas delivery from the ANAESTHETIC GAS DELIVERY SYSTEM or an auxiliary means stops, or is switched to alternative supplies like gas cylinders.

Subclause 201.11.8.102 ALARM CONDITION for POWER SUPPLY failure

The requirement for the duration of this ALARM SIGNAL is consistent with the pneumatic loss of pressure ALARM SIGNAL ("Ritchie whistle"). See also 201.12.4.107.1.

Subclause 201.11.8.103 INTERNAL ELECTRICAL POWER SOURCE

Many contemporary ANAESTHETIC WORKSTATIONS and their individual components have built-in INTERNAL ELECTRICAL POWER SOURCES. It is mandatory for the OPERATOR to be able to determine whether sufficient power is available for the task at hand. Otherwise the RISKS from unexpectedly running out of power would be unacceptably high, even if backup power is immediately available.

OPERATORS of an ANAESTHETIC WORKSTATION and its individual components, running on internal power, have to be made aware that this supply is nearing depletion to allow them to make provisions for the ANAESTHETIC WORKSTATION and its individual components failing to operate.

Subclause 201.12.4.101 Accidental adjustment of operating controls

Unacceptable RISKS to the PATIENT can occur when accidental adjustments of operating controls or accidental turning off of the ANAESTHETIC WORKSTATION or its individual components occurs. To control this RISK, the design of the OPERATOR-EQUIPMENT INTERFACE needs to prevent accidental adjustments. The USABILITY ENGINEERING PROCESS is used to ensure that these RISKS are reduced to acceptable levels. Examples of methods could include mechanical control techniques such as locks, shielding, friction-loading and detents, as well as for pressure-sensitive finger pads, capacitive finger switches and microprocessor-oriented “soft” controls.

When mechanical controls are used, it is important to ensure that controls are firmly engaged in the intended positions to prevent an undefined and potentially hazardous intermediate state. For controls with more than two intended positions, bi-stable should be interpreted to mean stable in each position and not stable in any intermediate position.

Subclause 201.12.4.102 Additional requirements for ANAESTHETIC WORKSTATIONS

This particular standard provides specific requirements for individual components which, although individual devices in their own right, can be utilized, in conjunction with other relevant devices, to form an ANAESTHETIC WORKSTATION.

Subclause 201.12.4.104.1 Accuracy

In previous standards, the expiratory volume ranges in Table 201.103 were referenced by the terms “adult”, “paediatric”, and “neonatal”. In this International Standard, those terms were replaced with the relevant DELIVERED VOLUME ranges because there is no international agreement as to what the terms “adult”, “paediatric”, and “neonatal” mean.

With regard to accuracy of expired volume measurement, although current technology allows for much higher accuracies, these cannot be met under every condition. Low prices and increased robustness may require less accuracy. Therefore, the accuracy requirement is maintained at this level.

Subclause 201.12.4.105 ANAESTHETIC BREATHING SYSTEM integrity ALARM CONDITION

The committee generally agreed that currently there is no way to indicate reliably the failure of ANAESTHETIC BREATHING SYSTEM integrity (for example, partial or even complete disconnection of the ANAESTHETIC BREATHING SYSTEM). Under certain circumstances, the monitoring of abnormal or low values of carbon dioxide, pressure, exhaled volume, concentration of vapour or oxygen can individually or in combination indicate or contribute to the detection of loss of ANAESTHETIC BREATHING SYSTEM integrity. It is for these reasons that a MEDIUM PRIORITY ALARM CONDITION is required, but that a specific method of determining or labelling of that ALARM CONDITION is not specified.

Subclause 201.12.4.106 ANAESTHETIC BREATHING SYSTEM continuing-positive pressure ALARM CONDITION

A minimum of 17 s delay is a compromise between immediately alarming to annunciate a HAZARDOUS SITUATION and avoidance of nuisance alarms. The wording “shall not exceed … two breaths” allows the MANUFACTURER to adapt the delay to, for example, synchronized ventilation modes with two breaths per minute.

Interruption of ventilation caused, for example, by an occlusion of the expiratory limb, is a major RISK that is mitigated by an ANAESTHETIC BREATHING SYSTEM continuing-positive-pressure ALARM CONDITION.

Subclause 201.12.4.107.2 Oxygen supply failure PROTECTION DEVICE

The oxygen supply failure PROTECTION DEVICE permits the remaining oxygen, when the oxygen supply is below the RATED pressure, to be safely delivered to the PATIENT in this emergency situation. The oxygen supply failure PROTECTION DEVICE should attempt to maintain an oxygen concentration above 19 %. The oxygen supply failure TECHNICAL ALARM CONDITION would have already generated a warning prior to the operation of this PROTECTION DEVICE.

Subclause 201.12.4.107.3 Hypoxic mixture delivery selection PROTECTION DEVICE

An hypoxic PROTECTION DEVICE has been mandated, as an alarm alone is not considered sufficient to prevent such accidents. A potential use error is closing of, for example, the oxygen delivery valve instead of the nitrous oxide valve. An hypoxic mixture delivery selection PROTECTION DEVICE either prevents this by not allowing the selection of hypoxic mixtures or via a pneumatic element that proportionally reduces the carrier gas fraction when the oxygen flow is reduced.

Subclause 201.12.4.108. PROTECTION DEVICE for the workplace environment

Both nitrous oxide and halogenated volatile agents create potential occupational health HAZARDS. Therefore, the MANUFACTURER of an ANAESTHETIC WORKSTATION has to provide means to reliably route excess gases to an ANAESTHETIC GAS SCAVENGING SYSTEM.

Subclause 201.13.101 Simultaneous failure

The purpose of this requirement is to ensure that failure of the ANAESTHETIC WORKSTATION control function can be detected by the corresponding MONITORING EQUIPMENT or ALARM SYSTEM or prevented by a PROTECTION DEVICE. When, for example, a single sensor is used both as feedback for a control function and as input for the ALARM SYSTEM, a single failure or degradation can allow an undetected hazardous output. As a result, such construction is not permitted.

Subclause 201.14.6.1 Identification of known and foreseeable HAZARDS

RF wireless technology is increasingly being incorporated into ME EQUIPMENT and ME SYSTEMS. There are concerns, which should be addressed, about the potential effects of the use of this technology on the ability of the ANAESTHETIC WORKSTATION and its individual components to function properly and the resultant safety of PATIENTS and OPERATORS.

Subclause 201.16.101.4 Connection for remote control

Control of the ANAESTHETIC WORKSTATION from a distance may reduce the exposure of OPERATORS to HAZARDS, for example radiation during a radiological PROCEDURE.

The MANUFACTURER has to do a careful RISK ANALYSIS to prevent technical failure and use errors.

Subclause 201.101.2 Interruption of the electrical POWER SUPPLY

Most mechanical/pneumatic ANAESTHETIC GAS DELIVERY SYSTEMS are independent from electrical power. These devices do not need any special precautions. For an electronically operated ANAESTHETIC GAS DELIVERY SYSTEM an “alternative means of gas delivery” can be, for example:

— an automatic switch-over to pure oxygen and a TECHNICAL ALARM, or

— a TECHNICAL ALARM and an alternative, manual gas delivery unit, or

— a TECHNICAL ALARM CONDITION and an external oxygen cylinder with PRESSURE REGULATOR and flow-metering device and labelling advising the OPERATOR to have this ready.

SUBCLAUSE 201.101.4.1.4 RESERVE OXYGEN SUPPLY

This is to protect the PATIENT in case of a failure of the primary source of oxygen.

Subclause 201.101.6.3 Carbon dioxide flow rate adjustment control

The first time the 600 ml/min limit for carbon dioxide appeared in a standard was in a December 1990 amendment to BS 4272-3[20]. This requirement was in response to reports of over delivery of carbon dioxide.

Subclause 201.101.8 Oxygen flush

Oxygen flush is used to rapidly fill the ANAESTHETIC BREATHING SYSTEM with oxygen and flush other ANAESTHETIC GASES out of the ANAESTHETIC BREATHING SYSTEM.

Subclause 201.101.9 FRESH-GAS OUTLET

An OPERATOR-accessible FRESH-GAS OUTLET should have a means to prevent unintentional disconnection of the FRESH-GAS OUTLET connector.

Subclause 201.102.2.1 MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

This PROTECTION DEVICE provides the ultimate fail-safe pressure protection in the case of failure of the adjustable pressure limitation (see 201.102.2.2).

Subclause 201.102.2.2 Adjustable pressure limitation PROTECTION DEVICE

The committee chose to include a requirement for an OPERATOR-adjustable pressure-limiting PROTECTION DEVICE to ensure that the OPERATOR has better control of maximum pressure. The adjustable pressure limitation can be used as the functional pressure limitation during normal operation in some modes of operation.

Subclause 201.102.4 Electrical conductivity

Burns can occur if antistatic or electrically conductive BREATHING TUBES are used while high-frequency electric surgery equipment is in use. Therefore, such BREATHING TUBES are not recommended.

Subclause 201.102.5.3 Reservoir bag connection port

During the development of this International Standard, the requirement for the reservoir bag connection port to be “within 20° of the vertical axis” was questioned. Some members of the working group felt the requirement was unnecessarily design restrictive. In the end, the majority of the working group members concluded that this requirement is an important and effective deterrent against accidental misconnections of other parts of the ANAESTHETIC BREATHING SYSTEM to the reservoir bag connection port.

A reservoir bag on the PATIENT side of either the inspiratory or expiratory valve fills with exhaled gas, which is then re-breathed on subsequent inhalation.

Subclause 201.102.5.6 Inspiratory and expiratory port connectors of a CIRCLE ABSORBER ASSEMBLY

During the development of this International Standard, the requirement for the “axis of these ports to be within ±50 ° of the horizontal plane” was questioned. Some of the working group members felt the requirement was unnecessarily design restrictive. In the end, the majority of the working group members concluded that this requirement is an important and effective deterrent against accidental misconnections of other parts of the ANAESTHETIC BREATHING SYSTEM to the inspiratory or expiratory port connectors of a CIRCLE ABSORBER ASSEMBLY. It also prevents kinking of the breathing tubes.

Subclause 201.102.6 Leakage

The limit of 150 ml/min for an entire ANAESTHETIC BREATHING SYSTEM was established for two reasons:

— to restrict the loss of gas volume intended to be delivered to the PATIENT, and

— to limit ANAESTHETIC GAS pollution in the area of the ANAESTHETIC WORKSTATION.

This limit was considered to be the maximum acceptable in view of all the other potential sources of gas leaks. Individual component limits were not established to allow flexibility in design; for example, a design can include a swivel adapter on the Y-PIECE, a potential source of increased leak, provided the rest of the components or connections of the ANAESTHETIC BREATHING SYSTEM leak minimally.

Subclause 201.102.7 Inspiratory and expiratory pressure/flow rate characteristics

Total expiratory and total inspiratory resistance are established at a maximum of 6 hPa (6 cmH_2O) each in order to limit the work of breathing for the spontaneously breathing PATIENT and to restrict positive end-expiratory pressure. In setting the maximum, the Committee considered the resistances of commercially available components and selected a value between those considered and the ideal of zero resistance. This limit is considered to be the generally acceptable maximum physiological value by clinicians. Since there are cases where one would require an ANAESTHETIC BREATHING SYSTEM with resistance much less than the maximum or require the use of components that would increase the resistance above the maximum, the requirement for disclosure of the AIRWAY PRESSURE/airway flow rate characteristics is included.

Subclause 201.102.8.1 Y-PIECE

The recess is a RISK CONTROL measure against the accidental disconnection of the Y-PIECE and the BREATHING TUBE.

Subclause 201.102.8.2 Exhaust valve

An open EXHAUST VALVE between the inspiratory valve and the Y-PIECE permits free return of exhaled gas into the inspiratory pathway with subsequent rebreathing.

Although evaluating the performance of an EXHAUST VALVE under wet conditions would be a better model of real usage with a PATIENT, wet condition testing yields inconsistent results that are not reproducible. Consequently, the disclosure requirement is based on testing performed under dry conditions.

Subclause 201.102.9.1 Constructional requirements

Ensuring unidirectional flow prevents undesirable rebreathing. Misassembling the ANAESTHETIC BREATHING SYSTEM into hazardous configurations is prevented by requiring valves to be non-interchangeable.

To prevent operation with exhausted, desiccated or no absorbent, the OPERATOR needs to be able to readily see the presence and colour of the absorbent.

Subclause 201.102.9.2 Absorbent bypass mechanism

Ensuring that the absorbent bypass control is firmly engaged and obvious to the OPERATOR prevents unintended, undesirable rebreathing including undefined and potentially hazardous intermediate states. Ensuring that gas does not flow to the absorbent when the control is in the "off" position permits changing the absorbent without polluting the local atmosphere or interrupting the flow of gases to the PATIENT.

Subclause 201.102.10.1 Constructional requirements

A malfunction of these valves can cause rebreathing that is difficult to correct. Requiring that the OPERATOR be able to see the action of these valves is the most practicable means of RISK CONTROL. Many valve designs are orientation-sensitive. Consequently, they need to be placed in a fixed orientation and that makes the Y-PIECE an inappropriate location for such valves.

A Y-PIECE with valves could be placed in reverse orientation to another set of UNIDIRECTIONAL VALVES on a CIRCLE ABSORBER ASSEMBLY, making ventilation impossible.

Subclause 201.102.10.4 Reverse flow rate and dislocation

Reverse flow, dislocation, or ineffectiveness of unidirectional inspiratory or expiratory valves can result in rebreathing of expired gases that causes a reduction of carbon dioxide elimination. The most significant leak with disk-type valves can be at low pressures, whereas with flap valves, the most significant leak can be closer to a pressure of 5 hPa (5 cmH_2O). A 60 ml/min reverse flow rate is considered clinically acceptable and attainable using current manufacturing techniques.

Subclause 201.102.11 FRESH-GAS INLET

If the FRESH-GAS INLET is placed on the PATIENT side of the expiratory valve, loss of FRESH GAS through the EXHAUST VALVE will occur. If the FRESH-GAS INLET is placed between the expiratory valve and the absorbent, the humidification of the FRESH GAS mixture will be enhanced; however, with this arrangement, loss of FRESH GAS through the EXHAUST VALVE can occur if the EXHAUST VALVE is not placed at a sufficient distance from the FRESH-GAS INLET. Placement of the FRESH-GAS INLET on the PATIENT side of the inspiratory valve permits the FRESH GAS flow to pass by the Y-PIECE during exhalation. This prevents the use of a spirometer in the expiratory limb of the ANAESTHETIC BREATHING SYSTEM.

Subclause 201.103.6.2 Outlet connectors

The use of differing connectors is intended to prevent connection to an inappropriate DISPOSAL SYSTEM. See also ISO 7396-2 and ISO 9170-2.

Subclause 201.104.1.1 Marking

The delivery of the vapour of a volatile anaesthetic agent can be hazardous to the PATIENT, OPERATOR and others in the vicinity. The OPERATOR needs to understand the proper operation and the maintenance of an ANAESTHETIC VAPOUR DELIVERY SYSTEM prior to operating it. Consequently, following the instructions for use is considered as a mandatory action for the safe operation of an ANAESTHETIC VAPOUR DELIVERY SYSTEM.

Subclause 201.104.2.2 Accuracy

To control the RISK associated with under or over delivering the vapour of a volatile anaesthetic agent, agent-specific calibrated controls are required on an ANAESTHETIC VAPOUR DELIVERY SYSTEM.

Subclause 201.104.3 Vapour output during and after oxygen flush

There are HAZARDS that can arise from interaction between a conventional ANAESTHETIC VAPOUR DELIVERY SYSTEM and the oxygen flush on an ANAESTHETIC WORKSTATION, for example:

— if the ANAESTHETIC VAPOUR DELIVERY SYSTEM is mounted downstream of the oxygen flush, the high flow rate (75 l/min) during a flush can cause the mass output from the ANAESTHETIC VAPOUR DELIVERY SYSTEM to increase; in some cases this could force liquid anaesthetic agent out of the ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— if the ANAESTHETIC GAS DELIVERY SYSTEM PIPING has a high resistance to flow, the pressure at the ANAESTHETIC VAPOUR DELIVERY SYSTEM during a flush can be high enough to cause a so-called “pumping effect” which can increase the output concentration of the ANAESTHETIC VAPOUR DELIVERY SYSTEM.

ISO 5358:1980[2] had requirements to address these HAZARDS in that 19.4 required the flow of gas from the oxygen flush to be delivered to the FRESH-GAS OUTLET without passing through any ANAESTHETIC VAPOUR DELIVERY SYSTEM. It also required that the pressure at the ANAESTHETIC VAPOUR DELIVERY SYSTEM not be greater than 100 hPa (100 cmH_2O) during a flush. This 100 hPa (100 cmH_2O) helped determine the safety of an ANAESTHETIC VAPOUR DELIVERY SYSTEM in that 15.10 required the ANAESTHETIC VAPOUR DELIVERY SYSTEM to be tested with a pressure fluctuation of 100 hPa (100 cmH_2O) without the output changing by more than 20 %.

ISO 5358:1992[3] kept the requirement that the flow of gas from the oxygen flush be delivered to the FRESH-GAS OUTLET without passing through an ANAESTHETIC VAPOUR DELIVERY SYSTEM and that the pressure at the ANAESTHETIC VAPOUR DELIVERY SYSTEM not be greater than 100 hPa (100 cmH_2O) during a flush, but the pressure fluctuation test for the ANAESTHETIC VAPOUR DELIVERY SYSTEM was changed to 50 hPa (50 cmH_2O). This meant the 100 hPa (100 cmH_2O) test was no longer matched to an ANAESTHETIC VAPOUR DELIVERY SYSTEM test. This was probably an oversight, as the pressure fluctuation test was mainly concerned with the effects of ANAESTHETIC VENTILATORS.

The first ANAESTHETIC VAPOUR DELIVERY SYSTEM test proposed provided a 100 hPa (100 cmH_2O) pressure fluctuation test for an ANAESTHETIC VAPOUR DELIVERY SYSTEM to ensure it was compatible with an ANAESTHETIC WORKSTATION that was designed to accept an OPERATOR-removable ANAESTHETIC VAPOUR DELIVERY SYSTEM.

This provided pneumatic requirements for ANAESTHETIC VAPOUR DELIVERY SYSTEM MANUFACTURERS and ANAESTHETIC WORKSTATION MANUFACTURERS which would ensure compatibility if different MANUFACTURERS' products were connected together. This is equivalent to the original requirements found in ISO 5358:1980.

This test does not specify pressures or locations of ANAESTHETIC VAPOUR DELIVERY SYSTEM but specifies that the output of the ANAESTHETIC VAPOUR DELIVERY SYSTEM does not vary by more than a specified amount both during and after oxygen flush. This gives greater flexibility for new designs (which can be insensitive to high pressure and high flow rates) without risking compatibility problems with older designs.

Subclause 201.105.2.2 Adjustable pressure limitation PROTECTION DEVICE

The relationship between the OPERATOR-adjustable pressure limitation PROTECTION DEVICE and the pressure MONITORING EQUIPMENT and its ALARM LIMITS is not addressed in this International Standard. This is because of the differing ways in which pressure limitation can be used in clinical practice.

Subclause 201.105.7 Timed ventilatory pause

Pausing mechanical ventilation is necessary for certain clinical PROCEDURES.

EXAMPLE Chest x-ray at OPERATOR-chosen level of inflation, chest x-ray at end expiration, measuring central venous pressure or cardiac output, measuring respirophasic blood pressure variation, suctioning the airway, turning the PATIENT.

Currently, in order to avoid nuisance ALARM SIGNALS and to avoid cycling the ANAESTHETIC VENTILATOR while the ANAESTHETIC BREATHING SYSTEM is disconnected from the PATIENT, OPERATORS usually turn off the ANAESTHETIC VENTILATOR and thereby incur the RISK of undetected prolonged apnoea by subsequently forgetting to turn the ANAESTHETIC VENTILATOR back on.

Alternatively, the x-ray technicians manually attempt to synchronize chest x-ray exposure to ventilatory phase through hand-eye coordination, with varying effectiveness. Automated synchronization of x-ray exposure and ventilation would provide clinical benefits.

In addition, there are situations where, to permit the minimum disruption of ventilation, the initiation of the ventilatory pause needs to come from external equipment. This is particularly important for those PROCEDURES where the OPERATOR needs to evacuate the immediate area or when manual synchronization would be less effective, such as with high doses of radiation.

As part of the RISK MANAGEMENT PROCESS, special attention should be paid to ensuring that the PATIENT'S lungs remain adequately ventilated when either externally generated or repetitive ventilatory pauses occur.

The expiratory pause should be capable of being provided with a NETWORK/DATA COUPLING as specified in ASTM F2761-09, for example.

Subclause 201.105.8 Subatmospheric pressure

During closed suctioning PROCEDURES, where an external suctioning device is introduced into the airway to remove secretions while the ANAESTHETIC VENTILATOR is connected to the PATIENT, high subatmospheric pressures can develop. Suctioning PROCEDURES are regarded as expected NORMAL USE by an OPERATOR. It is recommended that the ANAESTHETIC BREATHING SYSTEM and the pressure transducers be able to withstand a

pressure of 100 hPa to 400 hPa (100 cmH_2O to 400 cmH_2O) below ambient pressure. The suctioning is hazardous itself but should not have a negative impact on the ANAESTHETIC BREATHING SYSTEM during the suctioning PROCEDURE. There are known to have been deaths when pressure transducers have failed after closed suctioning.

Subclause 208.5.2.2 Technical description

Testing of ALARM SYSTEMS and ALARM CONDITIONS helps to prevent unnoticed failure of important monitoring functions. If not performed automatically by the ANAESTHETIC WORKSTATION or its individual components, the RESPONSIBLE ORGANIZATION has to ensure regular testing. Therefore, detailed information about these tests is necessary. Such tests will usually be too complex to be performed by the OPERATOR, and providing the information in the technical description is therefore considered sufficient.

Subclause 208.6.8.3 Global indefinite ALARM SIGNAL inactivation states

Incidents repeatedly occur when alarms are permanently disabled. These incidents can be easily prevented by restricting the functions to ALARM OFF for individual parameters only and time-limited global audio pause functions.

Subclause 208.6.8.4 Termination of inactivation of ALARM SIGNALS

Permitting very long pauses of ALARM SIGNALS can be hazardous for the PATIENT since the OPERATOR will not be notified of the existence of an ALARM CONDITION. However, PATIENT management often requires delicate PROCEDURES that can be disrupted by auditory ALARM SIGNALS. Therefore, extending AUDIO PAUSED by OPERATOR action is useful to prevent the ANAESTHETIC WORKSTATIONS from disturbing the OPERATOR or others in the vicinity (e.g. surgeon).

Subclause 208.6.12 ALARM CONDITION logging

Optimal management of a PATIENT requires the ability to review the history of important ALARM CONDITIONS. This is a more reasonable means of RISK CONTROL in the clinical environment for a LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM than LATCHING ALARM SIGNALS. Additional information is also found in IEC 60601-1-8:2006, Annex A, for 6.12.

Annex BB
(normative)

Test for flammability of anaesthetic agent

BB.1 General

The following tests can be used to determine whether anaesthetic agents shall be regarded as non-flammable.

NOTE Cyclopropane and diethyl-ether are known to be flammable agents. Halothane, desflurane, sevoflurane, enflurane, and isoflurane have been found to be non-flammable agents.

BB.2 Spark ignition tests

Spark ignition tests shall be carried out with the most ignitable concentration of the anaesthetic agent mixed with the gases oxygen and/or nitrous oxide in which the anaesthetic agent is more ignitable using the test apparatus described in Annex F of IEC 60601-1:2006, and in IEC 60079-11.

With an ignition probability of less than 10^{-3}, ignition shall not occur:

— in a resistive circuit at a d.c. voltage of 20 V with a current of 1,0 A and at a d.c. voltage of 100 V with a current of 0,15 A;

— in an inductive circuit at a d.c. current of 200 mA with an inductance of 10 mH and at a d.c. current of 60 mA with an inductance of 1 000 mH;

— in a capacitive circuit at a d.c. voltage of 100 V with a capacity of 1 µF and at a d.c. voltage of 20 V with a capacitance of 20 µF.

The measuring circuits are illustrated in IEC 60601-1:2005, Figures G.4 and G.6.

BB.3 Surface temperature ignition tests

Determination of the ignition temperature shall be carried out with apparatus and PROCEDURES based on IEC 60079-20-1, with the following additional requirements:

— fill the test vessel with a mixture of oxygen and nitrous oxide in different proportions in successive tests, and

— cover the vessel with a lid which prevents diffusion but lifts easily if an explosion occurs.

The ignition temperature shall not be less than 300 °C.

Annex CC
(informative)

Environmental aspects

The environmental impact generated by the ANAESTHETIC WORKSTATION delivering anaesthesia is mainly isolated to the following occurrences:

— impact at local environment during NORMAL USE;

— use, cleaning and disposal of consumables during NORMAL USE;

— disposal at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this document addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages in the life cycle of the ANAESTHETIC WORKSTATION.

See Table CC.1 for a mapping of the life cycle of ANAESTHETIC WORKSTATIONS to aspects of the environment.

Table CC.1 — Environmental aspects addressed by clauses of this International Standard

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	209	201.11.101 201.102.3 201.104.7 209	201.5.101.1 201.7 209	209
2	Energy consumption	209	209	201.5.101.1 209	209
3	Emission to air	209	209	201.12.4.108 201.101.1.1 f), j) 201.101.5 201.102.6 201.103.3.1.4 201.103.3.1.5 201.10 201.11 202 209	209
4	Emission to water	209	209	209	209
5	Waste	209	209	209	209

Table CC.1 (*continued*)

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
6	Noise	209	209	201.9.2.104 201.11.8.102 201.11.8.103 201.12.4.102 201.12.4.104.2 201.12.4.105 201.12.4.106 201.12.4.107.1 201.105.8 208 209	209
7	Migration of hazardous substances	209	209	201.7.2.105 201.7.9.2.14 ee), gg) 201.11.6.8 209	209
8	Impacts on soil	209	209	209	209
9	Risks to the environment from accidents or misuse	209	209	201.11.6.8 201.11 209	209

Annex DD
(informative)

Reference to the essential principles

This document has been prepared to support the essential principles of safety and performance of ANAESTHETIC WORKSTATIONS as MEDICAL DEVICES according to ISO/TR 16142:2006. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006. Other means are possible. Table DD.1 maps the clauses and subclauses of this document with the essential principles of ISO/TR 16142:2006.

Table DD.1 — Correspondence between this document and the essential principles

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
A.1	IEC 60601-1:2005 201.4.3 201.12 201.13 201.108 206	This standard is embedded in the IEC 60601-1 series. Manufacturers of medical devices have, among others, to comply with quality management system standards such as ISO 13485
A.2	IEC 60601-1:2005 201.4.3 201.12.4 201.13 201.101 201.102 201.103 201.104 201.105 208	
A.3	IEC 60601-1:2005 201.12.4 201.101 201.102 201.103 201.104 201.105 208	
A.4	IEC 60601-1:2005, in particular: 4.9, 11.6.6 15.2 15.3.7 and 201.12	

Table DD.1 (*continued*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
A.5	IEC 60601-1:2005, in particular: 3.44 15 and 201.7 201.11.101	
A.6	IEC 60601-1:2005, in particular: 4.2 and 201.108	
A.7.1	IEC 60601-1:2005, in particular: 11.4 11.6.6 11.6.7 11.6.8 11.7 15.3 and 201.7.2.105 201.11.6.8	
A.7.2	IEC 60601-1:2005, in particular: 11.6.6 and 201.11.101	
A.7.3	IEC 60601-1:2005, in particular: 11.4 11.6.6 11.6.8 11.7 and 201.11.6.8	
A.7.4	Not applicable	See also Pharmacopeia and publications of authorities responsible for medicinal products/drugs
A.7.5	IEC 60601-1:2005, in particular: 11.6.8 11.7 and 201.11.6.8	
A.7.6	IEC 60601-1:2005, in particular: 11.6 and 201.11.6.3	
A.8.1	IEC 60601-1:2005, in particular: 12.2 11.6.6 11.6.7 and 206	See A.8

Table DD.1 (*continued*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
A.8.1.1	Not applicable	See also A.8
A.8.1.2	Not applicable	See A.8
A.8.2	IEC 60601-1:2005, in particular: 7.2.17 and 201.11.101	See A.8
A.8.3	Not applicable	See A.8
A.8.4	Not covered	See also A.8
A.8.5	IEC 60601-1:2005, in particular: 7.2.17 and 201.11.101	
A.8.6	IEC 60601-1:2005, in particular: 7.2.17	See note on labelling in A.13.1
A.9.1	IEC 60601-1:2005, in particular: 16 and 201.8 201.9 201.12 201.16	IEC 60601 (all parts)
A.9.2	IEC 60601-1:2005, in particular: 4 4.1 4.2 4.3 4.4 4.5 4.7 4.9 and 201.12	IEC 60601 (all parts) including collateral standards
A.9.3	IEC 60601-1:2005, in particular: 11.4 and 201.101.1.1 Annex BB	IEC 60601 (all parts)
A.10.1	IEC 60601-1:2005, in particular: 12 and 201.12 201.101 201.102 201.103 201.104 201.105	

Table DD.1 (*continued*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
A.10.2	IEC 60601-1:2005, in particular: 12.2 and 206	
A.10.3	IEC 60601-1:2005, in particular: 7.4 and 201.7.4.3	
A.11.1	IEC 60601-1:2005, in particular: 10 and 202	IEC 60601 (all parts)
A.11.2.1	not applicable	IEC 60601 (all parts)
A.11.2.2	not applicable	IEC 60601 (all parts)
A.11.3	IEC 60601-1:2005, in particular: 10 and 202	IEC 60601 (all parts)
A.11.4	IEC 60601-1:2005, in particular: 7 and 201.7	IEC 60601 (all parts)
A.11.5.1	not applicable	IEC 60601 (all parts)
A.11.5.2	not applicable	IEC 60601 (all parts)
A.11.5.3	not applicable	
A.12.1	IEC 60601-1:2005, in particular: 14 and 201.14	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts) IEC 60601-1-4
A.12.2	IEC 60601-1:2005, 201.7.2.103 201.105.6 201.105.7	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.3	IEC 60601-1:2005, in particular: 7.9.2.4 8.2 15.4.4 and 201.11.8 201.11.8.102 201.11.8.103	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)

Table DD.1 (*continued*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
A.12.4	IEC 60601-1:2005, in particular: 4 7 12 and 201.12 201.101 201.102 201.104 201.105 208	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.5	IEC 60601-1:2005, in particular: 10 17 and 202	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.6	IEC 60601-1:2005, in particular: 8 and 201.8	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.7	IEC 60601-1:2005, in particular: 9 11 13.2 15 and 201.7 201.9	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.7.1	IEC 60601-1:2005, in particular: 9 15 and 201.9	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.7.2	IEC 60601-1:2005, in particular: 9 and 201.9	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)

Table DD.1 (*continued*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
A.12.7.3	IEC 60601-1:2005, in particular: 9 and 201.9	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.7.4	IEC 60601-1:2005, in particular: 7 8 16.9 and 201.101 201.102 201.103 201.104 201.105 206	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.7.5	IEC 60601-1:2005, in particular: 11.1	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.8	IEC 60601-1:2005, in particular: 7 12 and 201.107 201.12 201.101 201.102 201.103 201.104 201.105 206	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.8.1	IEC 60601-1:2005, in particular: 12 and 201-12	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)

Table DD.1 (*continued*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/Notes
A.12.8.2	IEC 60601-1:2005, in particular: 12 and 201.12 201.101 201.102 201.103 201.104 201.105 206 208	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.12.8.3	IEC 60601-1:2005, in particular: 7 and 201.107 206	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 (all parts) IEC 60601 (all parts) IEC 61010 (all parts)
A.13.1	IEC 60601-1:2005, in particular: 7 and 201.107 206	
A.14.1	201.108	

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[8] ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

[9] ISO/TR 14969, *Medical devices — Quality management systems — Guidance on the application of ISO 13485:2003*

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Alphabetized index of defined terms used in this particular standard

BSN
BADAN
STANDARDISASI
NASIONAL